Kentucky Health Care Improvement Authority

February 23, 2012 ~ 12:00 pm

Capitol Annex ~ Room 113

Minutes of Meeting

Members Attending:
Sharon Clark, Commissioner ~ Chair
Beth Jurek, proxy for Secretary Janie Miller
Tricia Okeson, proxy for Dr. Steve Davis
Karen Jones
Dr. Connie White

Members Absent:
Dr. Edward Halperin
Dr. Frederick de Beer
Senator Julie Denton
Senator Denise Harper Angel
Representative Ron Crimm
Representive Jim Gooch
Dr. Jann Aaron
Wilma Peeples
Dr. Dirck Curry
Mariann Dunn

Call to Order ~
Commissioner Clark called the meeting to order.

Roll Call / Welcome ~
The roll was taken; a quorum was not present. The meeting was adjourned and the following general discussion was held:

General Discussion ~
Commissioner Clark welcomed Dr. Connie White to her first meeting. As orientation for the new member, representatives from the four program areas provided an overview of the programs that are overseen by the Kentucky Health Care Improvement Authority.

Quarterly reports of the programs were distributed to the members; however they were not discussed in detail. Copies of the reports are attached.

At the last meeting, a discussion was held about approved drug disposal sites. Information about approved sites across the Commonwealth was distributed to the members by Kentucky ASAP.

Announcements ~
The next meeting is scheduled for May 8, 2012 at 1:30 pm in the Hearing Room at the Department of Insurance.

Submitted By:	Approved By:
/s/ DJ Wasson	/s/ Sharon P. Clark
2/23/12	7/20/12
Date	Date

Kentucky Health Care Improvement Authority

Kentucky Agency for Substance Abuse Policy (KY-ASAP)
February 23, 2012

1. ***Please summarize any progress or achievement toward the goals of your program that have been met during this reporting period.***

   - KY-ASAP was created in 2000 to develop a strategic plan to reduce the prevalence of tobacco, alcohol and other drug use among youth and adult populations in Kentucky. The agency was reorganized into the Justice and Public Safety Cabinet on July 9, 2004, by Executive Order 2004-730.

   - Since that date, KY-ASAP has successfully designated 75 boards in 113 counties.

   - KY-ASAP continues to strive for further accountability and accessibility by visiting and presenting information and training to local boards.

   - On May 6, 2011 10 KAR 7:010 & 7:020 were repealed. These regulations were replaced by 500 KAR 20:010 and 500 KAR 20:020.

   - All KY-ASAP local boards remain in compliance with state regulations.

   - Fulton County has turnd in all documents necessary to begin the designation process. However, the State KY-ASAP office awaits receipt of additional information.

   - KY-ASAP continued its collaboration with the Kentucky Crime Prevention Coalition, the Kentucky Schools Board Association and others to bring the 2nd annual Kentucky Youth Leadership Symposium to Frankfort on June 27th & 28th, 2011. This year's main topic will be underage drinking prevention.

   - KY-ASAP continues its collaboration with the Kentucky Center for School Safety (KCSS) to provide free training opportunities to KY-ASAP Local Boards. Through this collaboration, staff of the KY-ASAP State office will volunteer to organize, prepare and work at various trainings offered by KCSS and in return the registration fee for these trainings will be waived for local KY-ASAP boards.

   - In 2012, 24 Local KY-ASAP Boards will reach their 10 year anniversaries.

   - The Office of Drug Control Policy in collaboration with the Partnership for a Drug-Free America continues its statewide PSA campaign to bring professionally produced localized media messages to supportive media partners in a sustained effort to reduce the incidence of substance abuse in the Commonwealth. Our collaboration with the Partnership for a Drug Free America continues to bring over $6 million in professionally produced PSAs.

     The tremendous benefits that we receive from the Partnership allow us to counter any and all negative messages with positive prevention strategies.

This is an excellent opportunity for a positive story on another initiative KY-ASAP & the ODCP is doing to support the reduction of youth & adult substance use.

Addiction is the single greatest preventable illness in the country, and like other diseases, it affects not just the person with the illness but also family and friends. Parents are more pressed for time than ever, and in addition to finding the time to talk with their children about the health risks of drugs and alcohol, they tell us they need new information, tools, support and help on what to say and do.

Because our mission is to serve as a leader and catalyst for improving the health and safety of all Kentuckians by promoting strategic approaches and collaboration to reduce drug use and related crime this is a perfect opportunity for the ODCP/KY-ASAP to collaborate and be apart of such an important and proactive issue.

ODCP/KY-ASAP continues to take advantage of the many collaborative opportunities and outreach responsibilities it has to share our mission regarding prevention, treatment, and law enforcement. It is necessary for us to be able to disseminate that information statewide. Some of the exciting initiatives that have moved this project to the next level and reaching more people in the Commonwealth are:

1. AdSpace Mall Network – Fayette Mall
2. UL Student Center Digital Signage Network
3. UK Student Center Digital Signage Network
4. National Cinemedia Theatres (Louisville, Lexington, Paducah, Richmond)
5. Great Escape Theatres / UniqueScreen Media (Bowling Green, Madisonville)
6. ScreenVision Theatres (Harlan, Hopkinsville, Maysville, Florence)

We can assure the KHCIA that the use of these funds have been and will continue to be well spent with the Partnership for A Drug-Free Kentucky and feel very encouraged and inspired with our ability to make a difference.

- The Kentucky Agency for Substance Abuse Policy continues to strive for maximum accountability by updating forms and requiring additional detail from local boards.

- The next Kentucky State ASAP board meeting will be held on Thursday, May 17, 2012.

2. *Please indicate any challenges that were encountered during this reporting period related to the program's goals and objectives, administration or other project factors?*

- As always, the ever-changing complexions of the local boards create challenges to the day-to-day administrative function of KY-ASAP. As boards continually update their membership and officer rosters, KY-ASAP likewise must strive to keep its databases and distribution lists current. Challenges to

this goal may exist when communication between the local board and KY-ASAP is not properly maintained.

3. ***Please provide a report on the expenditure of tobacco settlement funds during this reporting period.***

   - Attached hereto as Attachment A, please find the account summary that outlines expenditure activity through January 31, 2012.

4. ***Please indicate if your program has met the requirement to hold a public hearing on the expenditure of funds during this reporting period. If so, please include documentation regarding the hearing (for example, notices publicizing the hearing, handouts, minutes, media coverage, etc.) Please indicate any comments received, positive or negative, on the proposed use of funds.***

   The KY-ASAP State Board meets quarterly and receives a budget report. The most recent public meeting was held on August 16, 2011. The next public meeting will take place at the Kentucky Health Care Improvement Authority in August 2012.

KY-ASAP: Account Summary – Fiscal Year 2012 – July 1, 2011 thru Jan. 31, 2012

Description	Amount
Projected Annual Allotment	$1,923,400.00
SFY2012 BEGINNING BALANCE *(Projected)*	**$1,923,400.00**
Salary & Fringe	$35,427.70
Annual Allocations to Local Boards	$1,322.100.00
Supplies	$79.20
Board Meetings	$495.00
In-State Travel (Employee)	$1,449.20
Board Member Travel to Board Meetings	$677.74
Partnership for a Drug-Free Kentucky	$12,551.03
TOTAL EXPENDITURES	**$1,372,779.87**
BALANCE (as of 01-31-2012)	**$550,620.13**

Kentucky Lung Cancer Research Program

Second Quarter Report

FY2012

University of Kentucky

Lucille Parker Markey Cancer Center

for

Kentucky Health Care Improvement Authority

And

The KLCR Program Governance Board

Council for Postsecondary Education

Submitted:

January 16, 2012

Kentucky Health Care Improvement Authority

Tobacco Settlement Funding Report

Kentucky Lung Cancer Research Program
University of Kentucky
Second Quarter Report
FY 2012

1. Please summarize any progress or achievement toward the goals of your program that have been met during this reporting period.

The Kentucky Lung Cancer Research Program at the University of Kentucky/Markey Cancer Center (MCC) has five primary components:

A. An Administrative component
B. A component targeted toward attainment of National Cancer Institute Designation
C. The Kentucky Clinical Trials Network
D. A Core Program/Project Support component
E. An Investigator-Initiated project component

Progress in these areas is summarized as follows:

A. Administration

This component continued to oversee and support progress in the functions of all institutional elements of the program, as well as to coordinate activities with the University of Louisville.

B. National Cancer Institute Designation

Significant activity supporting our NCI designation efforts occurred within the second quarter of FY 2012. Several of these activities are outlined below.

1. MCC administration continued monthly research program leader meetings to discuss strategic planning efforts related to the MCC's growth, development and goal of obtaining NCI designation.
2. Proceeding with the pursuit of NCI designation, the MCC external advisory board meeting occurred on November 3, 2011. Prior to the meeting, the advisors received a developed version of the cancer center support grant application, which stimulated insightful discussion from the advisors during the meeting. After receiving productive comments, the advisory board has agreed that MCC is ready to proceed with submitting a cancer center support grant application in September 2012.
3. Since the external advisory board meeting on November 3, 2011, MCC Administration has facilitated the organization of working groups that are fine-tuning each section of the cancer

center support grant application. MCC administration will continue to assist with the development of the cancer center support grant.

4. MCC administration continues to provide monthly reports (eg, grant funding and clinical trial accrual reports) to program and shared resource leaders in order to facilitate open dialog and productive activities toward developing strategic research areas.
5. MCC has continued an active program of weekly scientific seminars. Once a month, this program is dedicated to a Distinguished Visitor Seminar Series.
6. UK HealthCare launched a new website design during this quarter which included a redesign of all the UK HealthCare service lines (eg, the MCC). MCC administration will continue to upgrade and more fully develop our website offerings (new material, etc.) on this newly designed site.
7. Recruitment efforts reported last quarter continued for key positions in Hematology/Oncology, molecular oncologic signaling and drug development. In addition, recruitment efforts began for two basic science faculty positions (one in the area of redox injury and repair and the other in lung cancer) and a population science faculty position.
8. A list of cancer-related scientific papers published and/or first appearing during this report period is included in Attachment I.
9. A list of lung cancer-related grants active during this report period is included in Attachment II.
10. The Fall edition of the MCC quarterly newsletter is included as Attachment III.

C. Kentucky Clinical Trials Network

The Kentucky Clinical Trials Network (KCTN) fulfills a legislative mandate through the Kentucky Lung Cancer Research Program to *"establish a statewide clinical trial network to make university-based clinical trials available to the community physician in order to bring the most innovative cancer treatments to all Kentuckians in need of these treatments."*

The KCTN functions as an engaged alliance of regional, local and university hospitals in partnership with community physicians for the execution of promising clinical trials throughout the Commonwealth. The network agenda is guided by the interests and expertise of multiple specialty healthcare professionals, including: pulmonologists, medical oncologists, radiologists, and surgeons.

The Network leadership team for this continually developing program facilitates identification and development of collaborative projects across disciplines, supported by the operational infrastructure of the KCTN Coordinating Center.

Quarterly Milestones:

- Operations:
  - **KCTN Sites have enrolled 552 patients to KCTN studies in 70/120 counties (58% of state)**
  - KCTN Coordinating Center Team conducted 18 Site Visits in 2nd quarter FY2012; regular Interim Site Visits, Education Site Visits, specific Study Support Site Visits, Study Monitoring Visits, Quality Review Visits, and Onboarding Visits.

- Project Assistance to non-KCTN project: Markey Cancer Center's Lung Initiative Project; drafted Project Management Plan, Monitoring & Quality Plan, and Communication Plan.
- Site Spotlights:
  - OMHS:
    - Hiring new Research Nurse - Priority focus on accrual to KCTN trials.
    - Priority - ↑accrual, ↑# therapeutic trials. Required next CoC 2015
  - Onboarding Site: Hazard Appalachian Regional Hospital
    - Establishing Research at facility
    - Contract executed
    - Primary Interests Interventional Trials
    - Nicola Jabbour, MD; Ray Elsouedi, MD
- Prospective Sites in Onboarding: Primary Interests Interventional Trials
  - Owsley Brown Cancer Center, Jewish Hospital, St. Mary's Healthcare, Kentuckiana Cancer Institute, Cancer & Blood Specialists - robust research program
    - Renato LaRocca, MD; Alfonso Cervera, MD; Amir Harandi, MD
- Central Recruitment Support:
  - Attend weekly UK lung conference to identify potential study candidates for external sites.
  - Assist sites with screening, prn; Attend Tumor Boards based on trials open.
- Events:
  - Markey Cancer Center Multidisciplinary Lung Cancer Symposium "Evolving Strategies in Lung Cancer Diagnosis & Treatment" - 7-8 Oct
    - 15 KCTN members participated
    - KCTN Program Information table
  - Markey "Side Effects of Cancer Therapy Chemo Brain"– 14 Oct
    - 2 KCTN members participated
  - Free to Breath- Lung Cancer Walk (NLCP) 13 Nov; KCTN table
  - Regional IRB Consortium - Fall 2011/Winter2012
    - Representatives from 14 Ky IRBs & KCTNCC
    - Agenda: Advanced Notice of Proposed Rule Making (ANPRM) regarding significant changes to Common Rule. Continue discussion regarding central IRB for Ky. multi-site studies.

- Study Spotlights:
  - "STEREOtactic Radiation and Adjuvant Chemotherapy in Lung Cancer (STEREO)": Investigator-Initiated Trial
    - Study Chair: Goetz Kloecker, MD – Brown Cancer Center
    - Patient Population: Early Stage deemed medically inoperable
    - Primary Endpt: Evaluate feasibility of adjuvant chemotherapy after stereotactic body radiation therapy for early stage NSCLC.
    - Secondary Endpts:
      - Safety of these sequential modalities.
      - Disease-free survival (DFS) and overall survival (OS)
      - Quality of life (QOL)
      - Biological and clinical markers for toxicity and DFS and OS
      - Protocol adherence of patients and providers
    - Utilized collaborative Project Development Team to finalize trial design.

- Due to limited availability of SBRT (a highly specialized radiation therapy) will utilize blended engagement model to expand access to trial.

- o **"**Survey of Primary Care Physicians' Attitudes Toward Systemic Therapy for Lung and Breast Cancer" - evaluate if the unawareness or perceptions about beneficial systemic therapy persists in the era of targeted therapy, and if academic PCPs have a different perception than community PCPs.
  - Study Chair: Goetz Kloecker, MD – Brown Cancer Center
  - 323 Kentucky physician completed surveys received; not reported in program accrual metrics in section 4. Screening & Accrual of this report.
  - Data analysis indicate -
    - Academic & Community PCPs very often not aware of curative and palliative benefits of systemic therapy.
    - Half of PCPs refer symptomatic advanced disease to palliative care without referral to medical oncology
  - Opportunity: This persistent lack of awareness by PCPs requires more educational effort by medical oncologists and academic insititutions
  - Plan: Evaluating options to expand and target outreach and CE to evaluate improvement
  - ASCO Abstract submitted

- o Therapeutic Intervention Study: *CTN-0501, "Randomized Phase II Trial of Carboplatin and Gemcitabine with or without Dexamethasone in Patients with Untreated Stage IIIB-pleural effusion and Stage IV Non-Small Cell Lung Cancer"* to examine reduction in blood toxicities and increased effectiveness of anti-tumor effects of chemotherapy when given with/without dexamethasone prior to chemotherapy.
  - Study Chair: John Rinehart, MD – Markey Cancer Center
  - Patient Population: Untreated & Recurrent Stage IIIB/IV, NSCLC
  - 9 Sites participated (located in every federal congressional district)
  - 60 Patients enrolled (patients enrolled from 31 counties)
  - Project Funding: KCTN (primary sponsor) & Eli Lilly
  - Study Findings: Data analysis indicate statistically significant differences between study arms for primary endpoints of hematologic toxicity in favor of patients in dexamethasone arm. Reduces grade 3 & 4 hematologic toxicities. Despite 3-fold advantage in Partial Response rates and OS in favor of Arm 2 (Dex), the differences are not statistically significant, (however, final survival analysis is pending; 4 patients [2 Dex and 2 No-Dex] remain on follow-up. Patient3 enrolled December 2006, randomized to receive Dex, completed all protocol therapies and continues on survival follow-up). Cost effective addition to therapy (alternative to growth factor and platelet transfusion support), approximately $6.40/cycle.
  - Manuscript submitted to Journal of Clinical Oncology, 29July2011.

- Pipeline Development:
  - o Attended Protocol Review Meetings at Markey Cancer Center to evaluate trial opportunities and engage KCTN in selected trials; Protocols pending receipt.
  - o Initiated development of IIT concept: Collaborative -Markey Biospecimen Shared Resource Facility and Cancer Control Program. KLCRP Cycle 11 grant submission.

- Screening & Accrual: **KCTN Sites have enrolled 552 patients to KCTN studies in 70/120 counties (58% of state)**

  - Period (1 Oct 2011 – 31 Dec 2011): Accrual: 18 / Screened: 42

  - Total Accrual & Screening:

Accrual by Sponsor Type	**2nd Quarter FY 2012**	**Program (FY2005 – FY2011)**
Investigator-Initiated	9	426
Screened	22	
Pharmaceutical & Cooperative Grp	9	126
Screened	20	
Accrual by Protocol Type	**1st Quarter FY 2012**	**Program (FY2005-FY2011)**
Therapeutic Intervention	9	181
Screened	22	
Non-Interventional	9	371
Screened	20	

- Study Pipeline-Open Trials:

Treatment Study: *CTN-0501, Chemotherapy with/without Dexamethasone.*
Patient Population: Untreated & Recurrent Stage IIIB/IV, NSCLC
Investigator-Initiated Study: John Rinehart, MD Study Chair
Study Plan: 9 Sites
Project Funding: KCTN & Eli Lilly
Preliminary data analysis indicate statistically significant differences between study arms for primary endpoints in favor of patients in dexamethasone arm. Data analysis indicate statistically significant differences between study arms for primary endpoints of hematologic toxicity in favor of patients in dexamethasone arm. Reduces grade 3 & 4 hematologic toxicities. Despite 3-fold advantage in Partial Response rates and OS in favor of Arm 2 (Dex), the differences are not statistically significant; however, final survival analysis is pending; 4 patients (2 Dex and 2 No-Dex) remain on follow-up. Cost effective addition to therapy (alternative to growth factor and platelet transfusion support), approximately $6.40/cycle. Manuscript submitted to Journal of Clinical Oncology, 29July (attached).

Subjects Accrued = 60

Epidemiology Study: *CTN-0601, Examining Lung Cancer Survival: Smoking Cessation, Quality of Life, Environmental Exposures*
Patient Population: Resected, Early Stage Lung Cancer
Investigator-Initiated Study: Claudia Hopenhayn, PhD
Study Plan: Conduct at 10 sites, N: 200 subjects
Project Funding: KCLRP Cycle 7 & KCTN

Subjects Accrued =181
Subjects Screened = 328

Treatment Study: *Phase III study to Assess Overall Survival of Patients receiving Maintenance Therapy of Allogeneic Tumor Cell Vaccine which demonstrates Enhancement of Tumor Antigen Recognition as a result of Transforming Growth Factor (TGF-β2) inhibition*
Patient Population: Maintenance Therapy in Stage IIIA, IIIB & IV NSCLC (stable disease or responded to 1st line platinum based chemotherapy)
Industry-Sponsored Study: NovaRx
Study Plan: Conduct at 2 sites, target enrollment 15
Project Funding: Industry, approximately $215,000 (10subjects), contingent upon number of patients enrolled & treatment milestone achieved

Subjects Accrued = 4
Subjects Screened = 6

Treatment Study: *Randomized, Double-blind, Placebo-controlled Study to Evaluate Long-term Safety & Efficacy of Darbepoetin Alfa Administered at 500µg Once-Every-3-Weeks in Anemic Subjects*
Patient Population: Stage III/IV NSCLC patients receiving multi-cycle Chemotherapy
Industry-Sponsored Study: Amgen
Study Plan: Conduct at up to 3 sites, target enrollment 27 subjects total
Project Funding: Industry, approximately $291,000/site

Subjects Accrued = 5
Subjects Screened = 45

Treatment Study: *Randomized, Open-label, Study of Platinum-based Chemotherapy Plus/Minus a Recombinant Human Anti-VEGFR-2 Monoclonal Antibody, IMC-112B*
Patient Population: 1st line, Recurrent or Advanced NSCLC
Industry-Sponsored Study: ImClone
Study Plan: Conduct at 1 site, target enrollment 4
Project Funding: Industry

Subjects Accrued = 0
Subjects Screened = 15

Treatment Study: *Randomized, Open-label, Study of Gemcitabine-Cisplatin Chemotherapy Plus/Minus Necitumumab (IMC-11F8), First-line Stage IV Squamous NSCLC*
Patient Population: 1st line, Stage IV Squamous NSCLC
Industry-Sponsored Study: ImClone
Study Plan: Conduct at 1 site, target enrollment 4
Project Funding: Industry

Subjects Accrued = 0
Subjects Screened = 12

Treatment Study: *Randomized Study of Sublobar Resection +/- Brachytherapy versus Stereotactic Body Radiation Therapy in High-Risk Patients with Stage I NSCLC*
Patient Population: Stage I NSCLC
Cooperative Group Sponsored Study: ACOSOG/RTOG
Study Plan: Conduct at 2 ACOSOG member sites, target enrollment 5
Project Funding: Cooperative Group

Subjects Accrued = 1
Subjects Screened = 2

Study: *Survey of Primary Care Physicians Attitudes Towards Systemic Therapy for Lung and Breast Cancers*
Population: Community based & Academic Primary Care Physicians in Kentucky
Investigator-Initiated Study: Goetz Kloecker, MD
Study Plan: Hard-copy & E-Surveys; KCTNCC & 2 sites, N: 300 subjects
Project Funding: KCTN survey production costs

Physicians Accrued = 323

Study Pipeline-Regulatory Start-Up:

Treatment Study: *STEREOtactic Radiation and Adjuvant Chemotherapy in Lung Cancer (STEREO)*
Patient Population: Early Stage NSCLC at high risk for microscopic metastatic disease
Investigator-Initiated Project: Goetz Kloecker, MD Study Chair
Study Plan: 65 patients at qualifying sites
Project Funding: Brown Cancer Center

Treatment Study: Randomized, Double-Blind, Efficacy & Safety Study of PF-00299804 versus Erlotinib for Treatment of Advanced NSCLC following Progression After, or Intolerance to, at least one prior Chemotherapy
Patient Population: Advanced, NSCLC following Progression or Intolerance
Industry-Sponsored Study: Pfizer
Study Plan: Conduct at 2 sites - UL and Kentucky Cancer Center
Project Funding: Industry, pending

Treatment Study: *Phase III, Comparison of Investigational Oral Agent to an Established Oral Agent in Patients with Progressive Disease Following at Least 4 cycles of Platinum-based Chemotherapy.*
Patient Population: Second-Line, NSCLC (Squamous Histology)
Industry-Sponsored Study: Boehringer Ingelheim
Study Plan: 5 sites
Project Funding: Industry, pending

Epidemiology Study: Building the Infrastructure for a Comprehensive Lung Cancer Data Source
Patient Population: Lung Cancer Patients & expand to other tobacco related disease sites
Investigator-Initiated Project: Claudia Hopenhayn, PhD & Joseph Pulliam, MD
Study Plan: Project Planning Team Working – collaborative shared resource facilities, Cancer Control and Biospecimen Core
Project Funding: Pending - Submit KLCRP Cycle 11 grant

Epidemiology Study: *Decision-Making on Biospecimen Collection & Use*
Patient Population: Lung Cancer Patients & General Population
Investigator-Initiated Project: Project Planning Team Working
Study Plan: In development, study design. KLCRP and NIH grant submission planned

Specimen-Collection Study: *Prospective Collection of Biospecimens; specimens banked and available to researchers examining lung cancer issues*
Patient Population: All Lung Cancers
Investigator-Initiated Project: Joseph Pulliam, MD
Study Plan: Pilot to ensure integrity of specimens; expand regionally. Pending protocol
Project Funding: Pending funding source

KCTN Study Sites:

University of Kentucky	Lexington
University of Louisville	Louisville
Owensboro Medical Health System	Owensboro
Cardiothoracic Surgical Specialists	Owensboro
Ohio Valley Surgical Specialists	Owensboro
Western Kentucky Hematology & Oncology Group	Paducah
St. Claire Regional Medical Center	Morehead
Montgomery Cancer Center	Mt. Sterling
King's Daughters Medical Center	Ashland
Tri-State Hematology & Oncology	Ashland
Kentucky Cancer Center	Hazard
Western Baptist Hospital	Paducah
St. Joseph Health System	Lexington
Surgical Associates of Lexington	Lexington
Flaget Memorial Hospital	Bardstown
Appalachian Regional Hospital – Hazard	Hazard
Commonwealth Cancer Center	Danville
Commonwealth Cancer Center	Frankfort
Commonwealth Cancer Center	Somerset

D. Core Program/Project Support Elements

1. "**Marty Driesler Lethal Cancers Project**"

Completion of this project continues to be ongoing; the program's status is, for the most part, static since last reporting period. Project staff continue to focus on quality assurance as data collection has ended and the project moves toward completion with satellite site study closures.

A major spin-off development from this project has been an exploration of potential accessory or independent environmental factors involved in the causation and /or development of lung cancer in the Fifth Congressional District of Southeastern Kentucky. Preliminary analyses have shown an unexplained mismatch between cigarette smoking rates and lung cancer incidence, suggesting the

involvement of one or more additional environmental factors. A detailed study was designed and developed to investigate potential linkages to heavy metals prevalent in the region and this project was submitted to the Department of Defense on October 1, 2010. The proposal has been funded and the study began on September 15, 2011.

2. Biospecimen Core Program

In support of multiple KLCR projects and an expanding translational research enterprise, the Markey Cancer Center continues to develop the Biospecimen Core Program (BCP) with the mission of collecting, annotating, storing, and distributing human-derived biological specimens to biomedical researchers. The BCP continues to be a critical resource for: 1) clinical correlative studies aimed at deciphering molecular signatures of tumors associated with a poor prognostic outcome and better therapeutic targeting; 2) identifying biomarkers for the risk assessment, early detection, and differential diagnosis of cancer; and 3) predicting and monitoring tumor responsiveness to chemotherapeutic and biologically-targeted treatments.

In the second quarter of 2012, collaborative efforts continued and expanded between the BCP of the Markey Cancer Center and the UK Department of Pathology in order to create a UK Medical Center- and Markey Cancer Center-integrated Biospecimen Core Shared Resource Facility (BCSRF). The BCP and BCSRF are sharing resources to facilitate the greater needs of biospecimen collection, storage, annotation and usage.

Our quarterly milestones include the following:

Between October and December, 2011, BCP employees discussed clinical research with 160 potential research participants and enrolled 106 patients. In addition to collecting 821 liquid and tissue biospecimen vials this quarter, BCP employees are continuing to improve the logistics and standard operating procedures of obtaining and distributing biospecimens to a greater number of biomedical researchers. Even though our consenting rate (66%) is slightly lower than the national average for biospecimen programs, after 6 quarters of high collections, our specimen collection has increased 7-fold showing higher efficiencies of biospecimen collection for each study subject.

The following table summarizes the cumulative participant accrual and biospecimen collection for the Versatile Protocol and several principal-investigator initiated studies (BUK, Driesler, SPN and Ovarian Screening). This table shows an overall increase of subjects by 4%. Accrual is open for the Versatile program, which shows a 2% increase of vial storage with a 9% increase of subjects.

Study	No. of Participants	No. of Vials in Storage
BUK 040447	343	6,674
Driesler 040714	252	15,220
SPN 020171	63	649

Versatile 040454	1,240	9,328
Ovarian Screening 050129	845	5,910
Total	**1,609**	**37,781**

The following table summarizes the number of participants in lung studies, showing an overall increase of 11% participants in three months, with a 22% increase of participants with lung ailments, specifically for the Versatile Protocol.

Study	No. of Participants
BUK 040447	343
Driesler 040714	252
SPN 020171	63
Versatile 040454	822
Total	**1,480**

For the study entitled “The Lung Cancer Research Initiative: A population-based case control-study of lung cancer in Appalachian Kentucky: The role of environmental carcinogens” the BCP received urine, hair, nail clippings, soil and water samples to set up the receipt and processing methodologies. BCP personnel processed 2 samples each, of EDTA- and heparin-preserved blood to initiate research support.

The Histopathology Unit continues to develop new procedures to support bench-to-bedside translational research. This quarter showed a 32% increase in unit-utilization.

Researcher	Project	Blocks	Slides	IHC	Other Stains
Arnold	s0819	1	36		
Chunming Liu		25	170		35
Evers	Spore	14	174		36
Evers, Mustain		6			
Evers, Saito	The Role of Adipose Tissue in Age-Dependent Severity to Critical Illness		48		
Evers, Valentino			560	56	51

Gao	NCI:R01 CA133429-01A1, ACS:RSG 0822001TBE	49			
Guo-Min Li			22		2
Gynecological Oncology	GOG	6	28		18
Leggas			106		
Massarweh	BRE-41		112	125	17
Massarweh	s1007	2			
Moscow	CD36, eNOS & Lipoprotein in vascular dysfunction		784		159
Mullett	calgb30506	1			
Pediatric Hematology/Oncology	COG	1	38		24
Radiation Medicine	RTOG 08-48	2	2		2
Rangnekar		22	68	74	
Romond	s1007	2			
Spear	Hepatocellular carcinoma (HCC) study	7	14		7
St. Clair, Evers	Developmental project for GI Spore		224	218	
	Total	138	2,386	473	351

The BCP continued to assist with other clinical studies. For the clinical trial entitled, “SWOG S0819: A Randomized Phase III Study Comparing Carboplatin/Paclitaxel or Carboplatin/Paclitaxel/ Bevacizumab with or without Concurrent Cetuximab in Patients with Advanced Non-Small Cell Lung Cancer (NSCLC)” BCP personnel processed 54 vials of biospecimens. Plasma and buffy coat samples were then returned to SWOG research coordinators for distribution to central laboratories. For the clinical study entitled “OVA2-001-CO3: Marker Discovery and Clinical Trial Testing for OVA2 using Serum from Women with a Documented Ovarian Adnexal Mass” two specimens were processed and shipped to a central laboratory. Participants recruited to each of these studies also donated biospecimens to the BCP’s Versatile Protocol. Four ascites fluid samples were dispensed for the study entitled “CA125/BDOT”.

As a new procedure of receiving tissue samples from outside sources for distribution to Markey Cancer Center researchers, 10 tissue samples were dispensed to one investigator, while 25 tissue samples were dispensed to a second investigator. These tissue samples were received on behalf of the future GI SPORE grant. Finally, 4 tissue samples were dispensed from the Versatile Protocol to a third investigator, in preparation for a grant application.

Fourteen letters of support were written by the Medical Director in support of grant applications for the NIH and KLCRP. These applications propose using BCP services for collection of preliminary data and for the fully funded study.

Annotation of tissue specimens with clinicopathological information is ongoing in collaboration with the Kentucky Cancer Registry (KCR), a statewide population-based central cancer registry that is

part of the National Cancer Institute's (NCI) Surveillance, Epidemiology, and End Results (SEER) Program. Additionally, the BCP continues to support the activities of other core units such as the Biostatistics/Bioinformatics Shared Resource Facility and the KCR through collaborative research support projects.

E. Investigator-Initiated Projects

UK released a call for proposals for Cycle 11 funding on November 7, 2011. Eighteen letters of intent to submit full proposals were received. Full applications are due January 12, 2011.

2. Please indicate any challenges that were encountered during this reporting period related to the program's goals and objectives, administration or other project factors.

Our current assessment of the primary challenges to enriching the lung cancer program include:

1. The decline in national funding (funding from all venues, both National Institutes of Health and foundation moneys, as well as pharmaceutical sources) for all cancers, but particularly in lung cancer, leads to more challenges in the research arena.
2. We will require a senior faculty member dedicated to lung cancer research that can coordinate our lung cancer research program's development and refinement. Further attention and strategic planning is needed to generally develop our lung cancer translational research program and build our portfolio of lung cancer clinical trials; identifying and developing personnel and other resources dedicated to this endeavor is a priority. These activities will be important as we proceed with plans to develop a UK lung cancer SPORE application. Recruitment for a senior-level lung cancer researcher is underway.
3. Greater interaction between basic scientists and clinicians is needed to develop novel clinical trials that enhance bench-to-bedside research.
4. To build more collaborative, multi-disciplinary teams that enhance our novel research initiatives, we require greater ability to network with other lung cancer clinical and basic researchers within our region.
5. New lung cancer screening trial results were made available that show an improvement in survival of 20%. This sets a new standard of using CT screening for lung cancer in high risk populations, but leaves many unanswered questions with regard to implementation of this new screening tool. No national guidelines have been developed and no third-party payors have issued guidance with regard to this new tool. This leads to many new questions, but also may allow for new avenues of research.

3. Please provide a report on the expenditure of tobacco settlement funds during this reporting period.

Financial Report
2nd Quarter FY2012
10/01/2011-12/31/2011
University of Kentucky

	Total Revenue FY2000-2012	Expenditures FY2000-2012	Encumbrances	Balance	2nd Quarter FY2012 Expenses	FY2012 Year-to-Date Expenses
Investigator-Initiated Grants	7,500,000.00	7,500,000.00	0	0	**0**	$ -
Prime Transfers	$ -					
KY Clinical Trials	$ 5,181,751.72	$ 4,134,481.89	$ 120,596.33	$926,673.50	$ 102,400.58	$ 203,254
NCI Designation	$ 4,862,237.02	$ 3,783,150.99	$ 702,108.11	$376,977.92	$ 351,100.00	$ 693,771
Administration	$ 1,628,088.80	$ 1,528,559.56	$ 49,009.90	$50,519.34	$ 44,976.62	$ 53,967
Marty Driesler	$ 574,482.02	$ 368,150.74	$ 57,321.46	$149,009.82	$ 28,931.28	$ 51,234
Biospecimen Core	$ 1,202,224.02	$ 1,078,662.73	$ 51,046.31	$72,514.98	$ 75,002.65	$ 151,178
TOTALS	**$ 20,948,783.58**	**$ 18,393,005.91**	**$ 980,082.11**	**$ 1,575,695.56**	**$ 602,411.13**	**$ 1,153,403**

As of December 31, 2011	Budget	Total Costs	Balance
Investigator-Initiated Grants	$1,569,086	$1,192,703	$376,383

4. Please indicate if your program has met the requirement to hold a public hearing on the expenditure of funds during this reporting period. If so, please include documentation regarding the hearing (for example, notices publicizing the hearing, handouts, minutes, media coverage, etc.) Please indicate any comments received, positive or negative, on the proposed use of funds.

The last meeting of the Council of Postsecondary Education's Kentucky Lung Cancer Research Governance Board was on September 28, 2011. The last meeting of the Kentucky Health Care Improvement Authority was on November 15th, 2011. From these meetings, the use of funds to enrich opportunities and activities related to the KTCN and Biospecimen Core Programs are being discussed and planned.

Current Members

Kentucky Lung Cancer Research Program Governance Board

Name	Representing
Carloss, Harry W., M.D., Chair	State-at-Large
Eaton, John W., Ph.D.	UofL
Evers, B. Mark, M.D.	UK
Flanagan, Dan	CPE

Graviss, Joe	CPE
Joshi, Rajan, M.D.	State-at-Large
Miller, Donald, M.D.	UofL
Mullett, Timothy W., M.D.	UK
Roach, James P., M.D.	State-at-Large

Attachment I

Second Quarter 2012 Report

Publications

Publications by Markey Authors
October – December 2011
(Lung cancer-related publications)

1. Gilliam LAA and St Clair DK. Chemotherapy-Induced Weakness and Fatigue in Skeletal Muscle: The Role of Oxidative Stress. Antioxidants & Redox Signaling 15:2543-63, 2011.
2. Nikolova-Karakashian MN and Reid MB. Sphingolipid Metabolism, Oxidant Signaling, and Contractile Function of Skeletal Muscle. Antioxidants & Redox Signaling 15:2501-17, 2011.
3. Smith JD, Moylan JS, Hardin BJ, Chambers MA, Estus S, Telling GC, et al. Prion Protein Expression and Functional Importance in Skeletal Muscle. Antioxidants & Redox Signaling 15:2465-75, 2011.
4. Fallah MP, Chelvarajan RL, Garvy BA and Bondada S. Role of phosphoinositide 3-kinase-Akt signaling pathway in the age-related cytokine dysregulation in splenic macrophages stimulated via TLR-2 or TLR-4 receptors. Mechanisms of Ageing and Development 132:274-86, 2011.
5. Mannino DM and Martinez FJ. Lifetime risk of COPD: what will the future bring? Lancet 378:964-5, 2011.
6. Zhu HP, Jeon HY, Chen Y, Ozkan E, Derksen RD, Reding ME, et al. Development of Two Intelligent Spray Systems for Ornamental Nursery and Fruit Tree Crops. Hortscience 45:S202-S, 2010.
7. Arsenescu V, Narasimhan ML, Halide T, Bressan RA, Barisione C, Cohen DA, et al. Adiponectin and Plant-Derived Mammalian Adiponectin Homolog Exert a Protective Effect in Murine Colitis. Digestive Diseases and Sciences 56:2818-32, 2011.
8. Blalock EM, Buechel HM, Popovic J, Geddes JW and Landfield PW. Microarray analyses of laser-captured hippocampus reveal distinct gray and white matter signatures associated with incipient Alzheimer's disease. Journal of Chemical Neuroanatomy 42:118-26, 2011.
9. Singh D, Orellana CF, Hu Y, Jones CD, Liu YF, Chiang DY, et al. FDM: a graph-based statistical method to detect differential transcription using RNA-seq data. Bioinformatics 27:2633-40, 2011.
10. Son YO, Wang X, Hitron JA, Zhang Z, Cheng SP, Budhraja A, et al. Cadmium induces autophagy through ROS-dependent activation of the LKB1-AMPK signaling in skin epidermal cells. Toxicology and Applied Pharmacology 255:287-96, 2011.
11. Wattamwar PP, Hardas SS, Butterfield DA, Anderson KW and Dziubla TD. Tuning of the pro-oxidant and antioxidant activity of trolox through the controlled release from biodegradable poly(trolox ester) polymers. Journal of Biomedical Materials Research Part A 99A:184-91, 2011.
12. Bacon M, Maul E, Pulliam J and D'Orazio J. Autoimmune Hemolytic Anemia in a 2-Year-Old Child With Pneumococcal Pneumonia. Clinical Pediatrics 50:974-7, 2011.
13. Beezhold K, Liu J, Kan H, Meighan T, Castranova V, Shi XL, et al. miR-190-Mediated Downregulation of PHLPP Contributes to Arsenic-Induced Akt Activation and Carcinogenesis. Toxicological Sciences 123:411-20, 2011.
14. Bruce-Keller AJ, Gupta S, Knight AG, Beckett TL, McMullen JM, Davis PR, et al. Cognitive impairment in humanized APP x PS1 mice is linked to A beta(1-42) and NOX activation. Neurobiology of Disease 44:317-26, 2011.
15. DeSimone CP, Day ME, Dietrich CS, Tovar MM and Modesitt SC. Risk for Residual Adenocarcinoma in Situ or Cervical Adenocarcinoma in Women Undergoing Loop Electrosurgical Excision Procedure/Conization for Adenocarcinoma in Situ. Journal of Reproductive Medicine 56:376-80, 2011.

16. Horton DB, Siripurapu KB, Zheng GR, Crooks PA and Dwoskin LP. Novel N-1,2-Dihydroxypropyl Analogs of Lobelane Inhibit Vesicular Monoamine Transporter-2 Function and Methamphetamine-Evoked Dopamine Release. Journal of Pharmacology and Experimental Therapeutics 339:286-97, 2011.
17. Li J, Harp C, Tharappel JC, Spear BT and Glauert HP. Effect of vitamin E on hepatic cell proliferation and apoptosis in mice deficient in the p50 subunit of NF-kappa B after treatment with phenobarbital. Food and Chemical Toxicology 49:2706-9, 2011.
18. Liu C, Xiong YL and Rentfrow GK. Kiwifruit protease extract injection reduces toughness of pork loin muscle induced by freeze-thaw abuse. Lwt-Food Science and Technology 44:2026-31, 2011.
19. Nam J, Perera P, Liu J, Rath B, Deschner J, Gassner R, et al. Sequential Alterations in Catabolic and Anabolic Gene Expression Parallel Pathological Changes during Progression of Monoiodoacetate-Induced Arthritis. Plos One 6:2011.
20. Pan JJ, Chang QS, Wang X, Son YO, Liu JK, Zhang Z, et al. Activation of Akt/GSK3 beta and Akt/Bcl-2 signaling pathways in nickel-transformed BEAS-2B cells. International Journal of Oncology 39:1285-94, 2011.
21. Rosewell K, Al-Alem L, Li FX, Kelty B and Curry TE. Identification of Hepsin and Protein Disulfide Isomerase A3 as Targets of Gelatinolytic Action in Rat Ovarian Granulosa Cells During the Periovulatory Period. Biology of Reproduction 85:858-66, 2011.
22. Shao Y, Wang ZZ and Zhang YM. Monitoring of liquid droplets in laser-enhanced GMAW. International Journal of Advanced Manufacturing Technology 57:203-14, 2011.
23. Wang X, Son YO, Chang QS, Sun LJ, Hitron JA, Budhraja A, et al. NADPH Oxidase Activation Is Required in Reactive Oxygen Species Generation and Cell Transformation Induced by Hexavalent Chromium. Toxicological Sciences 123:399-410, 2011.
24. Zhang Z, Wang X, Cheng SP, Sun LJ, Son YO, Yao H, et al. Reactive oxygen species mediate arsenic induced cell transformation and tumorigenesis through Wnt/beta-catenin pathway in human colorectal adenocarcinoma DLD1 cells. Toxicology and Applied Pharmacology 256:114-21, 2011.
25. Zhao RS, Hollis CP, Zhang H, Sun LL, Gemeinhart RA and Li TL. Hybrid Nanocrystals: Achieving Concurrent Therapeutic and Bioimaging Functionalities toward Solid Tumors. Molecular Pharmaceutics 8:1985-91, 2011.
26. Burd NA, Jeukendrup A, Reid MB, Burke LM, Stear SJ and Castell LM. A-Z of nutritional supplements: dietary supplements, sports nutrition foods and ergogenic aids for health and performance-Part 26. British Journal of Sports Medicine 45:1163-4, 2011.
27. Chen G, Ke ZJ and Luo J. NEUROPROTECTION TARGETING AT GSK3B. Alcoholism-Clinical and Experimental Research 35:281A-A, 2011.
28. Chen G, Ke ZJ, Wang X, Liao JM, Frank J, Bower K, et al. AUTOPHAGY-MEDIATED PROTEION AGAINST ETHANOL NEUROTOXICITY. Alcoholism-Clinical and Experimental Research 35:36A-A, 2011.
29. Crosby RA, Casey BR, Vanderpool R, Collins T and Moore GR. Uptake of Free HPV Vaccination Among Young Women: A Comparison of Rural Versus Urban Rates. Journal of Rural Health 27:380-4, 2011.
30. Fulkerson Z, Wu T, Sunkara M, Vander Kooi C, Morris AJ and Smyth SS. Binding of Autotaxin to Integrins Localizes Lysophosphatidic Acid Production to Platelets and Mammalian Cells. Journal of Biological Chemistry 286:34654-63, 2011.
31. Gedaly R, Angulo P, Hundley J, Daily MF, Chen CG and Evers M. IN VITRO AND IN VIVO STUDY OF PI-103 AND SORAFENIB ON INHIBITION OF HEPATOCELLULAR CARCINOMA PROLIFERATION AND TUMOR PROGRESSION. Hepatology 54:1306A-A, 2011.
32. Herrin DW, Ramalingam S, Cui Z and Liu J. Predicting insertion loss of large duct systems above the plane wave cutoff frequency. Applied Acoustics 73:37-42, 2012.

33. Jaeger LB, Dohgu S, Sultana R, Lynch JL, Owen JB, Erickson MA, et al. Lipopolysaccharide alters the blood-brain barrier transport of amyloid b protein: A mechanism for inflammation in the progression of Alzheimer's disease (vol 23, pg 507, 2009). Brain Behavior and Immunity 25:1737-, 2011.
34. Ke ZJ, Wang X, Liu Y, Fan Z, Chen G, Frank J, et al. ETHANOL INDUCES ENDOPLASMIC RETICULUM STRESS IN THE DEVELOPING BRAIN. Alcoholism-Clinical and Experimental Research 35:36A-A, 2011.
35. Martin JT, Reda H, Dority JS, Zwischenberger JB and Hassan ZU. Surgical Resident Training Using Real-Time Simulation of Cardiopulmonary Bypass Physiology with Echocardiography. Journal of Surgical Education 68:542-6, 2011.
36. Pratt MC, Kluemper GT, Hartsfield JK, Fardo D and Nash DA. Evaluation of retention protocols among members of the American Association of Orthodontists in the United States. American Journal of Orthodontics and Dentofacial Orthopedics 140:520-6, 2011.
37. Shang Y, Chen L, Toborek M and Yu GQ. Diffuse optical monitoring of repeated cerebral ischemia in mice. Optics Express 19:20301-15, 2011.
38. Vore M and Zhao TY. THE-24C>T SINGLE NUCLEOTIDE POLYMORPHISM (SNP) OF MULTIDRUG RESISTANCE PROTEIN 2 (MRP2, ABCC2) AFFECTS THE BINDING OF TRANSACTING FACTORS TO A RNA MOTIF IN MRP2 5 ' UTR AND DECREASES TRANSLATION OF THE DOWNSTREAM OPEN READING FRAME (ORF). Hepatology 54:723A-A, 2011.
39. Wang X, Ke Z, Chen G, Xu M, Bower K, Frank J, et al. ETHANOL-INDUCED NEURONAL OXIDATIVE STRESS IS MEDIATED BY CDC42-DEPENDENT ACTIVATION OF NADPH OXIDASE. Alcoholism-Clinical and Experimental Research 35:48A-A, 2011.
40. Xu M, Chen G, Bower K, Liao M, Ke ZJ, Frank J, et al. ETHANOL PROMOTES CANCER CELL INVASION BY DISRUPTING THE VASCULAR ENDOTHELIAL BARRIER. Alcoholism-Clinical and Experimental Research 35:180A-A, 2011.
41. Chen X, Zhao XY, Xiong Y, Liu JJ and Zhan CG. Fundamental Reaction Pathway and Free Energy Profile for Hydrolysis of Intracellular Second Messenger Adenosine 3 ',5 '-Cyclic Monophosphate (cAMP) Catalyzed by Phosphodiesterase-4. Journal of Physical Chemistry B 115:12208-19, 2011.
42. Chittuluru JR, Chaban Y, Monnet-Saksouk J, Carrozza MJ, Sapountzi V, Selleck W, et al. Structure and nucleosome interaction of the yeast NuA4 and Piccolo-NuA4 histone acetyltransferase complexes. Nature Structural & Molecular Biology 18:1196-U148, 2011.
43. Dhar SK, Tangpong J, Chaiswing L, Oberley TD and St Clair DK. Manganese Superoxide Dismutase Is a p53-Regulated Gene That Switches Cancers between Early and Advanced Stages. Cancer Research 71:6684-95, 2011.
44. Dragun AE, Huang B, Gupta S, Crew JB and Tucker TC. One Decade Later: Trends and Disparities in the Application of Post-mastectomy Radiotherapy (PMRT) since the Release of the American Society of Clinical Oncology (ASCO) Clinical Practice Guidelines. International Journal of Radiation Oncology Biology Physics 81:S556-S, 2011.
45. Gal J, Zhang JY, Kwinter DM, Zhai JJ, Jia HG, Jia JH, et al. Nuclear localization sequence of FUS and induction of stress granules by ALS mutants. Neurobiology of Aging 32:2011.
46. Gleason JF, Kudrimoti M, Van Meter EM, Mohiuddin M, Regine WF, Valentino J, et al. Low-dose Fractionated Radiation (LDFRT) as a Chemopotentiator of Neoadjuvant Paclitaxel and Carboplatin for Locally Advanced Squamous Cell Carcinoma of the Head and Neck: 5 Year Results Of A Prospective Phase II Trial. International Journal of Radiation Oncology Biology Physics 81:S502-S3, 2011.
47. Jin ZG, Mei WY, Strack S, Jia JH and Yang J. The Antagonistic Action of B56-containing Protein Phosphatase 2As and Casein Kinase 2 Controls the Phosphorylation and Gli Turnover Function of Daz Interacting Protein 1. Journal of Biological Chemistry 286:36171-9, 2011.

48. Kim K, Tsay OG, Atwood DA and Churchill DG. Destruction and Detection of Chemical Warfare Agents. Chemical Reviews 111:5345-403, 2011.
49. Li DM, Wu JZ, Zhang XR, Ma XF, Wingfield JC, Lei FM, et al. Comparison of Adrenocortical Responses to Acute Stress in Lowland and Highland Eurasian Tree Sparrows (Passer montanus): Similar Patterns During the Breeding, But Different During the Prebasic Molt. Journal of Experimental Zoology Part a-Ecological Genetics and Physiology 315A:512-9, 2011.
50. Miller RW and Ueland FR. Performance of the American College of Obstetricians and Gynecologists' Ovarian Tumor Referral Guidelines With a Multivariate Index Assay Reply. Obstetrics and Gynecology 118:1181-, 2011.
51. Miller RW and Ueland FR. Performance of the American College of Obstetricians and Gynecologists' Ovarian Tumor Referral Guidelines With a Multivariate Index Assay Reply. Obstetrics and Gynecology 118:1178-9, 2011.
52. Novak M, Jarrett SG, McCorkle JR, Mellon I and Kaetzel DM. Multiple mechanisms underlie metastasis suppressor function of NM23-H1 in melanoma. Naunyn-Schmiedebergs Archives of Pharmacology 384:433-8, 2011.
53. Ojeda L, Gao JL, Hooten KG, Wang EY, Thonhoff JR, Dunn TJ, et al. Critical Role of PI3K/Akt/GSK3 beta in Motoneuron Specification from Human Neural Stem Cells in Response to FGF2 and EGF. Plos One 6:2011.
54. Okamura D, Ienaga J, Starr ME, Evers BM and Saito H. A Murine Model of Acute Pancreatitis Demonstrating Age-dependent Increases in Mortality, Systemic Inflammation, and Activation of ERK and JNK. Pancreas 40:1345-, 2011.
55. Sekhar KR, Reddy YT, Reddy PN, Crooks PA, Venkateswaran A, McDonald WH, et al. The Novel Chemical Entity YTR107 Inhibits Recruitment of Nucleophosmin to Sites of DNA Damage, Suppressing Repair of DNA Double-Strand Breaks and Enhancing Radiosensitization. Clinical Cancer Research 17:6490-9, 2011.
56. Selever J, Gu GW, Lewis MT, Beyer A, Herynk MH, Covington KR, et al. Dicer-Mediated Upregulation of BCRP Confers Tamoxifen Resistance in Human Breast Cancer Cells. Clinical Cancer Research 17:6510-21, 2011.
57. Wang D, Ho A, Wu X, Hamilton A, Goodman M, Fleming S, et al. Results of Patterns of Care Study of Patients Treated with External Beam Radiotherapy for Prostate Cancer in 2004. International Journal of Radiation Oncology Biology Physics 81:S561-S2, 2011.
58. Burris JL and Andrykowski MA. Physical and Mental Health Status and Health Behaviors of Survivors of Multiple Cancers: a National, Population-Based Study. Annals of Behavioral Medicine 42:304-12, 2011.
59. Diaz-Guzman E, Zwischenberger JB and Hoopes CW. Lung Transplantation in Coal Workers Pneumoconiosis. Chest 140:1387-8, 2011.
60. Holley AK, Xu Y and St Clair D. Mechanisms of Manganese Superoxide Dismutase-Mediated Inside-Out Signaling in Skin. Free Radical Biology and Medicine 51:S123-S4, 2011.
61. Ludlam WH and Anthony L. Safety Review: Dose Optimization of Somatostatin Analogs in Patients with Acromegaly and Neuroendocrine Tumors. Advances in Therapy 28:825-41, 2011.
62. Miao L, Holley AK, St Clair DK and St Clair WH. Redox-mediated RelB-dependent regulation of Prostate Specific Antigen (PSA) gene expression in prostate cancer. Free Radical Biology and Medicine 51:S126-S, 2011.
63. Morgan ET, Sun HY, Kim KB and Lee CM. Reactive nitrogen species (RNS) in the regulation of cytochrome P450 proteolysis: NO hiding place for RNS-modified P450s. Drug Metabolism Reviews 43:24-5, 2011.
64. Spasojevic I, Miriyala S, Tovmasyan A, Salvemini D, Fan P, Vujaskovic Z, et al. Lipophilicity of Mn(III)N-Alkylpyridylporphyrins Dominates Their Accumulation Within

Mitochondria and Therefore in Vivo Efficacy: a Mouse Study. Free Radical Biology and Medicine 51:S98-S9, 2011.
65. Wiesner MR, Lowry GV, Casman E, Bertsch PM, Matson CW, Di Giulio RT, et al. Meditations on the Ubiquity and Mutability of Nano-Sized Materials in the Environment. Acs Nano 5:8466-70, 2011.
66. Butterfield DA. Proteomic Analysis of Brain from an Alzheimer Disease Transgenic Mouse Model with a Third Mutation in Amyloid Precusor Protein (M631L): in Vivo Effects of the Single Methionine Residue of A beta(1-42) and Relevance to Alzheimer Disease. Free Radical Biology and Medicine 51:S68-S9, 2011.
67. Christian WJ, Huang B, Rinehart J and Hopenhayn C. Exploring Geographic Variation in Lung Cancer Incidence in Kentucky Using a Spatial Scan Statistic: Elevated Risk in the Appalachian Coal-Mining Region. Public Health Reports 126:789-96, 2011.
68. Fleming ST, Love MM and Bennett K. Diabetes and Cancer Screening Rates among Appalachian and Non-Appalachian Residents of Kentucky. Journal of the American Board of Family Medicine 24:682-92, 2011.
69. Fleming ST, Schoenberg NE, Tarasenko YN and Pearce KA. Prevalence of Colorectal Cancer Screening Among a Multimorbid Rural Appalachian Population. Southern Medical Journal 104:811-8, 2011.
70. Hahn EJ, Rayens MK, Burkhart PV and Moser DK. Smoke-Free Laws, Gender, and Reduction in Hospitalizations for Acute Myocardial Infarction. Public Health Reports 126:826-33, 2011.
71. Hobbs J, Fardo DW, Cieply K, Dacic S, Hamilton RL and Horbinski C. GLIOBLASTOMA SURVIVAL VARIES ACCORDING TO DEGREE OF EGFR AMPLIFICATION. Neuro-Oncology 13:92-, 2011.
72. Miriyala S, Thipakkorn C, Xu Y, Noel T, Vander Kooi C, Batinic-Haberle I, et al. 4-Hydroxy-2-Nonenal Mediates Aifm2 Release From Mitochondria: An Insight Into the Mechanism of Oxidative Stress Mediated Retrograde Signaling. Free Radical Biology and Medicine 51:S30-S1, 2011.
73. Robinson RAS, Joshi G, Huang QZ, Sultana R, Baker AS, Cai J, et al. Proteomic analysis of brain proteins in APP/PS-1 human double mutant knock-in mice with increasing amyloid beta-peptide deposition: Insights into the effects of in vivo treatment with N-acetylcysteine as a potential therapeutic intervention in mild cognitive impairment and Alzheimer's disease. Proteomics 11:4243-56, 2011.
74. Romond J, Pulliam J and D'Orazio JA. Chest Wall Ewing Sarcoma Presenting as Abdominal Pain in a 12-Year-Old Boy. Journal of Pediatrics 159:1048-, 2011.
75. Salt EG, Crofford LJ, Studts JL, Lightfoot RW and Hall L. Development of a Quality Patient-Health Care Provider Communication Scale Based On Patients' Perspective. Arthritis and Rheumatism 63:2404, 2011.
76. Sultana R, Robinson RAS, Di Domenico F, Abdul HM, St Clair DK, Markesbery WR, et al. Proteomic identification of specifically carbonylated brain proteins in APP(NLh)/App(NLh) x PS-1(P264L)/PS-1(P264L) human double mutant knock-in mice model of Alzheimer disease as a function of age. Journal of Proteomics 74:2430-40, 2011.
77. Tarasenko YN and Schoenberg NE. Colorectal cancer screening among rural Appalachian residents with multiple morbidities. Rural and Remote Health 11:2011.
78. van Nagell JR, Miller RW, DeSimone CP, Ueland FR, Podzielinski I, Goodrich ST, et al. Long-Term Survival of Women With Epithelial Ovarian Cancer Detected by Ultrasonographic Screening. Obstetrics and Gynecology 118:1212-21, 2011.
79. Vanderpool RC, Casey BR and Crosby RA. HPV-Related Risk Perceptions and HPV Vaccine Uptake Among a Sample of Young Rural Women. Journal of Community Health 36:903-9, 2011.

80. Yang XY, Zhang XD, Heckmann BL, Lu X and Liu J. Relative Contribution of Adipose Triglyceride Lipase and Hormone-sensitive Lipase to Tumor Necrosis Factor-alpha (TNF-alpha)-induced Lipolysis in Adipocytes. Journal of Biological Chemistry 286:40477-85, 2011.
81. Zhu H, Zhao L, Wang E, Dimova N, Liu G, Feng Y, et al. The QKI-PLP pathway controls SIRT2 abundance in CNS myelin. Glia 60:69-82, 2012.
82. Agakishiev G, Aggarwal MM, Ahammed Z, Alakhverdyants AV, Alekseev I, Alford J, et al. Evolution of the differential transverse momentum correlation function with centrality in Au plus Au collisions at root s(NN)=200 GeV. Physics Letters B 704:467-73, 2011.
83. Baird WM, Siddens LK, Krueger SK, Larkin A, Swanson HI, Arlt VM, et al. Skin Carcinogenesis in Mice Following Application of Individual Polycyclic Aromatic Hydrocarbons (PAHs) and Environmental Mixtures. Environmental and Molecular Mutagenesis 52:S73-S, 2011.
84. Diaz-Guzman E, Khosravi M and Mannino DM. Asthma, Chronic Obstructive Pulmonary Disease, and Mortality in the US Population. Copd-Journal of Chronic Obstructive Pulmonary Disease 8:400-7, 2011.
85. Holtman JR, Dwoskin LP, Dowell C, Wala EP, Zhang ZF, Crooks PA, et al. The novel small molecule alpha 9 alpha 10 nicotinic acetylcholine receptor antagonist ZZ-204G is analgesic. European Journal of Pharmacology 670:500-8, 2011.
86. Liu JY, Stevens PD, Li X, Schmidt MD and Gao TY. PHLPP-Mediated Dephosphorylation of S6K1 Inhibits Protein Translation and Cell Growth. Molecular and Cellular Biology 31:4917-27, 2011.
87. Mao CD and Byers SW. Cell-Context Dependent TCF/LEF Expression and Function: Alternative Tales of Repression, De-Repression and Activation Potentials. Critical Reviews in Eukaryotic Gene Expression 21:207-36, 2011.
88. McKenzie S, Nelson R, Mailey B, Lee W, Chung V, Shibata S, et al. Adjuvant chemotherapy improves survival in patients with American Joint Committee on Cancer stage II colon cancer. Cancer 117:5493-9, 2011.
89. Scott D, Rohr J and Bae Y. Nanoparticulate formulations of mithramycin analogs for enhanced cytotoxicity. International Journal of Nanomedicine 6:2757-67, 2011.
90. Seamon LG, Tarrant RL, Fleming ST, Vanderpool RC, Pachtman S, Podzielinski I, et al. Cervical cancer survival for patients referred to a tertiary care center in Kentucky. Gynecologic Oncology 123:565-70, 2011.
91. Wolf GT, Fee WE, Dolan RW, Moyer JS, Kaplan MJ, Spring PM, et al. NOVEL NEOADJUVANT IMMUNOTHERAPY REGIMEN SAFETY AND SURVIVAL IN HEAD AND NECK SQUAMOUS CELL CANCER. Head and Neck-Journal for the Sciences and Specialties of the Head and Neck 33:1666-74, 2011.

Attachment II

Second Quarter 2012 Report

Active Lung Cancer-Related Grants

Name	Title
Anderson, Bradley	The University of KY Cancer Nanotechnology Training Center (UK CNTC)
Arnold, Susanne	A population-based case-control study of lung cancer in Appalachian Kentucky: The role of environmental carcinogens
Bae, Younsoo	Controlled Inhibition of the Glycolytic Pathway for Lung Cancer-Targeted Therapy
Black, Esther	Inhibition of PI3K Using Isoform Selective Agents in NSCLC
Craven, Rolf	Stable Isotope-Derived Metabolomics to Elucidate the Mechanism of a Tumor-Associated Cytochrome in Lung Cancer Growth and Metabolism
Evers, Bernard	Kentucky Lung Cancer Program, Prime Account
Gairola, Chandrachuranan	Activation of the Par-4 Extrinsic Pathway of rSuppression of Lung Cancer
Hirschowitz, Edward	Bionanoconjugates for Detection of Circulating Tumor Cells in Lung Cancer
Hirschowitz, Edward	Autoantibodies in NSCLC as Markers of Disease
Hopenhayn, Claudia	Lung cancer survival in Kentucky: a multifactorial approach
Lee, Wooin	Immunoproteasome in Lung Cancer
Rangnekar, Vivek	Activation of the Par-4 Extrinsic Pathway of rSuppression of Lung Cancer
Roszman, Thomas	Inhibition of Lung Cancer Cell Migration/Invasion by Cell Penetrating Peptides
Schoenberg, Nancy	Faith Moves Mountains: A CBPR Appalachian Wellness & Cancer Prevention Program
Shi, Xianglin	The Mechanism of Arsenic-Induced Cell Transformation
Studts, Jamie	Development of a Conjoint Analysis Instrument for Lung Cancer Screeening Decisions
Wang, Zhigang	Rev1 and Carcinogen-Induced Lung Cancer
Yannelli, John	Combined Orally Administered Yeast-derived 3-Glucan with 1650 Tumor Vaccine in the Treatment of NSCLC
Zwischenberger, Joseph	Development of a Perfusion-Induced Systemic Hyperthermia Delivery Apparatus

Attachment III

Second Quarter 2012 Report

Markey Quarterly

renjith krishnan / freedigitalphotos.net

FALL | 2011

MARKEY *quarterly*

SEASONAL NEWS FOR MARKEY CANCER CENTER FACULTY AND STAFF

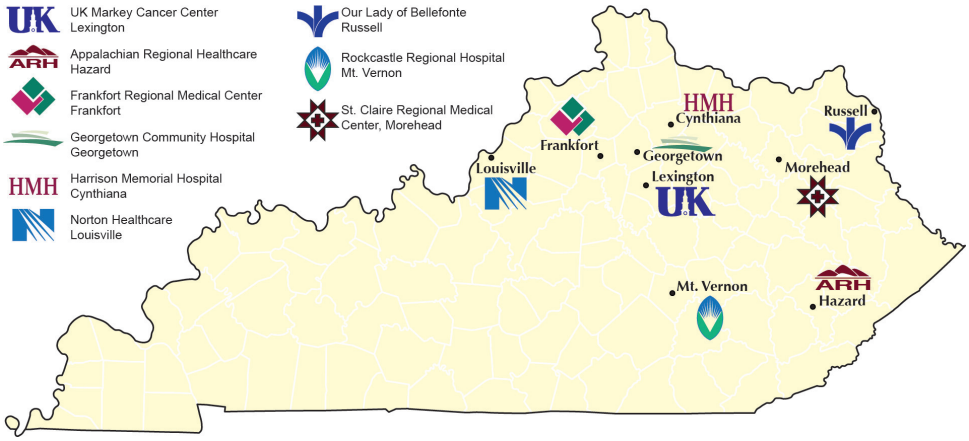
STATEWIDE OUTREACH

MARKEY AFFILIATE NETWORK BRINGS NEW OPPORTUNITES TO KENTUCKY HOSPITALS

The Markey Affiliate Network is growing - and continuing its vision of providing all Kentuckians access to excellent cancer care.

Most recently, the Markey Affiliate Network added Our Lady of Bellefonte Hospital in Greenup County to its network of hospitals, bringing the total number of Markey Affiliates to eight. And earlier this year, Dr. Dennie Jones joined the Markey team, leading the Markey Affiliate Network and its clinical outreach, research and education programs.

Those additions serve as momentum for the growing network. But besides providing high-quality clinical care at each affiliate site, Markey Affiliates are also beginning increased involvement in research. The Oncore Clinical Trials Database is active at most affiliate sites, and Dr. Jones expects the first trial to open before the end of 2011.



Plans for the network's future include identifying funding opportunities to involve affiliate sites in patient navigator and telegenetics programs. In addition, Markey would like to enhance telemedicine efforts network-wide, and offer continuing education programs such as tumor boards and physician board review courses at all affiliate sites.

Affiliated hospitals also participate in the Kentucky Cancer Program and Kentucky Cancer Registry, as well as the Ovarian Screening Program.

jscreationzs / freedigitalphotos.net

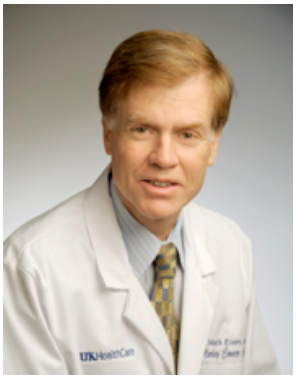
MARKEY BY THE NUMBERS

The number of Markey Affiliate Network hospitals added to the network since 2010 3

Number of new cancer cases in Kentucky, highest among states without an NCI-designated center 23,595

FROM THE DIRECTOR

B. MARK EVERS, MD, DIRECTOR, MARKEY CANCER CENTER



In so many ways, 2011 was a remarkable year for the Markey Cancer Center. I'm amazed at the challenging goals we've set for ourselves the past few years and all of the steps we've taken toward those goals during the past 12 months.

Take a look at just a few of the things we've accomplished in the last year:

- Took the pointed feedback of our NCI CCSG External Advisory Board from 2010 and improved upon our performance. At our recent 2011 meeting, our EAB told us that with a few key improvements, we're ready to submit our application for NCI designation in 2012.
- Submitted our Gastrointestinal SPORE grant for funding renewal. We should know the SPORE status early in 2012.
- Increased our overall research funding and our research funding from the NCI.
- Increased the number of patients we are enrolling in clinical trials, the number of outpatient cancer visits, outpatient chemotherapy visits and radiation medicine treatment visits.
- Established an ACS Patient Navigator Program.
- Recruited 14 new basic science investigators and 11 new clinicians.
- Opened the fourth and fifth floors of the BioPharm Complex, which will be used to house Markey investigators.
- Added three new hospitals (see the front page of this newsletter) to the Markey Affiliate Network, and added the Kailash Cancer Hospital (India) as our second "sister" center.
- Produced another record-breaking Cancer Research Day, which drew more posters in 2011 than in any previous year.
- Revamped the Markey Minute weekly electronic newsletter, and start producing this quarterly update to keep everyone informed about the great things happening at our cancer center.
- Supported the continued efforts of our fundraising community through countless projects and donations by Markey teams.

There are many more things that I haven't included – things that our faculty and staff are doing every day to make the Markey experience a great one. I would like to thank each of you for contributing to our success over the past year – what we've accomplished truly encompasses every one of us doing the best we can every day.

Now, we must look forward to 2012. It already is shaping up to be one of the biggest years in the history of the Markey Cancer Center – we have some incredibly important initiatives that will come to fruition in the coming year, and I hope we are all looking forward to adding some impressive things to our list of accomplishments. Let's keep our momentum strong.

MARKEY DIFFERENCE MAKERS

Congratulations to the following Markey Difference Makers. The Difference Maker of the quarter is Marcia Ballard. Marcia has been nominated for Difference Maker recognition four times recently.

Linda Anderson
Donna Areaux
Linda Baker
Marcia Ballard
Jean Barker
June Clopein
Felipa Cowan
Almita Cummins
Jenny Delap
Cassandra Dirks
David Faulconer
Robin Fisher
Susan Gibson
Donna Gilbreath
Daniel Grantz
Kennetha Hatton
Melissa Hounshell
Trisha Jackson
Charles Jenkins
Linda Leach
Stacey Montgomery
Renee Morff Rainey
Sue Mucha
Stephanie Mullins
Mincha Parker
Darlene Paskovics
Angela Pennington
Lori Peters Jordan
Mary Phillips
Laura Reichel
Kara Reynolds
Misti Rice
Jennifer Rogers
Sharon Schimmel
Gina Smithers
Dana Stafford
Kellie Thurman
Nathan Vanderford
Rachel Miller Ware
Melanie Wilson
Roger Yankey
Stephanie Zebosky

TELL US ABOUT IT

Do you have an idea for a future edition of Markey Quarterly? A picture you'd like to see included? Email Markey's Research Communications Office (mccrco@uky.edu) with your story idea.

MEET A MARKEY MOVER

DAVID LOCKHART, RADIATION MEDICINE

This quarter, Markey Quarterly introduces you to David Lockhart, Chief Radiation Therapist. David was nominated by Marcus Randall, MD, FACR, Markey Foundation Chair in Radiation Medicine and Professor and Chairman of the Department of Radiation Medicine.

"David possesses a rare combination of genuine caring for others plus exceptional technical leadership skills," Randall said.

"He leads a fantastic team of radiation therapists who often work in a very stressful environment and has earned everyone's respect by working very hard, setting a great example for others and treating everyone with respect. He is always willing to go the extra mile to take care of our patients."

Hi David. Thanks for talking with us. What's your background and where are you from originally?
I'm from Clintwood, a small town in the southwestern part of Virginia.

Where did you go to school?
I went to radiation therapy school at the Medical College of Virginia in Richmond, Va.

What brought you to UK?
There were few jobs in my field when I graduated. While visiting a cousin at UK's College of Pharmacy, I stopped by the department of Radiation Medicine and was lucky to find a radiation therapist position available. I've been here since I graduated in 1996.

What's your role in Radiation Medicine?
My role is to manage and supervise radiation therapists. There are nine therapists here at UK, and our outreach facilities in Morehead, Georgetown and Maysville each have two therapists who deliver radiation treatments. I am also part of our Radiation Department QA team and our Managerial Team that discusses and works to resolve departmental issues.

What role does Radiation Medicine play in patient care at MCC?
Our department plays a major role at Markey by delivering curative and palliative care radiation to many patients. We specialize in a number of treatments: brachytherapy implants for prostate and GYN cancers; stereotactic body radiation therapy (SBRT) for lung, liver and spine cancer; gamma knife radiosurgery for brain tumors; total body irradiation (TBI) for patients prior to a bone marrow transplant and a fair amount of pediatric radiation treatments.

What do you like most about your job?
In the department of Radiation Medicine, I work among the best radiation therapists out there. They make my job easier and deliver quality patient care to every patient. They really take pride in the their work, which makes me proud to be part of the team.

What do you like most about working at MCC?
The wide range and diversity of treatment modalities we provide is what I like most about working at Markey. The opportunity to offer the latest treatments used in the field today is very rewarding.

What do you like to do when you're not at work?
I love being a dad to my two young children. It is a full time job and there is never a dull moment. And in my free time, I try to play as much golf as possible.

What's your favorite food or meal?
My wife and I love good sushi.

What's your favorite song or artist?
If you looked at my programmed radio stations or iTunes, they would all be country.

What was the last movie you watched?
A few weeks ago, I took my two year old to see The Lion King in 3D.

Who should be the next Markey Mover?
Email Markey's Research Communications Office (mccrco@uky.edu) with your story idea.

NOTEWORTHY

WELCOME

Tadahide Izumi, PhD, Associate Professor, Toxicology
Jon Thorson, PhD, Professor, Pharmacology
Qiou Wei, PhD, Assistant Professor, Toxicology
Ying Liang, Internal Medicine
Heather Russell-Simmons, Research Communications Office

LEADERSHIP APPOINTMENTS

Marc Randall, MD, professor and Markey Foundation Endowed Chair in Radiation Medicine, UK HealthCare Chief of Ambulatory Services

Brett Spear, PhD, professor of Microbiology, Immunology and Molecular Genetics, Integrated Biomedical Sciences Director of Graduate Studies

PRESENTATIONS & PUBLICATIONS

Markey members published 107 manuscripts in peer-reviewed journals in July, August, September and October.

The article "6-Carboxyfluorescein and structurally similar molecules inhibit DNA binding and repair by O6-alkylguanine DNA alkyltransferase" by Manana Melikishvili, David W. Rodgers and **Michael G. Fried** was highlighted by the Faculty of 1000. The article appeared in DNA Repair earlier this year.

GRANTS

Susanne Arnold, MD, associate professor of Internal Medicine, and colleagues were awarded a grant by the Department of Defense to study potential environmental reasons for the high lung cancer rates in Eastern Kentucky. The grant is for $1.43 million over three years.

Gang Chen, PhD, research assistant professor of Internal Medicine, was awarded a total of $599,000 for fiscal year 2012 as part of a four-year grant totaling $599,000 from American Cancer Society for "The Mechanism of Arsenic-Induced Cell Transformation."

Hiroshi Saito, PhD, assistant professor of Surgery, was awarded a total of $304,425 for fiscal year 2012 as part of a five-year grant totaling $1,522,125 from National Institute on Aging for "The Role of Adipose Tissue in Age-dependent Sensitivity to Critical Illness."

Xianglin Shi, PhD, professor in the Graduate Center for Toxicology, was awarded a total of $334,125 for fiscal year 2012 as part of a five-year grant totaling $1,670,625 from National Institute of Environmental Health Sciences for "Prevention of UV-Induced Carcinogenesis by Cyan din-3-glucoside."

Haining Zhu, PhD, associate professor of Molecular and Cellular Biochemistry, was awarded a total of $324,844 for fiscal year 2012 as part of a five-year grant totaling $1,299,376 from National Institutes of Health for "Role of FUS in ALS."

AWARDS, RECOGNITIONS & SELECTIONS

Sue McFarlan received her CCRN® Nurse Executive-Board Certified status through the American Association of Critical-Care Nurses. CCRN certification is for nurses providing care to acutely and/or critically ill adult, pediatric and neonatal patients.

Photo courtesy of UK Public Relations

NEW MARKEY RESEARCH FLOORS OPEN IN BIOPHARM BUILDING

Markey Director Dr. Mark Evers (center) cuts the ribbon to open new two new research floors in the BioPharm complex on November 29. University of Kentucky President Eli Capilouto, Board of Trustees members and College of Pharmacy leadership also participated in the ceremony.

The new floors house research laboratories and office space for researchers in the College of Pharmacy and for the Markey Cancer Center.

Markey names Assistant Directors

WORKING ON UNIFIED FOCUS FOR NCI DESIGNATION

Markey has appointed three assistant directors, whose attention will be placed on Markey's vision and goals and aligning strategic cancer center efforts in relation to the 2012 application for NCI designation.

Beth Yost will serve as assistant director for finance, providing fiscal oversight of human resources and cancer center finances. She will also ensure compliance with college and university policies and collaborate with departments and colleges on financial matters.

Nathan Vanderford, PhD, will serve as assistant director for research, providing oversight, planning, development and evaluation of Markey's research endeavors. Most recently, he was supervisor of the Research Communications Office.

Carla Repass will serve as assistant director for administration, supervising the administrative functions of the director's office, engineering major cancer functions, connecting constituencies and overseeing special initiatives.

Earlier this year, leadership changes were announced for the Division of Medical Oncology. Dennie Jones, MD, became Interim Division Chief of Medical Oncology. He will oversee the continued growth of the division, including new faculty recruitment. Dr. Jones also retains his current role as Markey Deputy Director for Clinical Outreach, Research and Education, Director of the Markey Affiliate Network and Professor of Internal Medicine.

Susanne Arnold, MD, will serve as Associate Director for Clinical Research, and John Hayslip, MD, will serve as Director of the Clinical Research Organization and will be responsible for overseeing Clinical Care and Research Teams.

Beth Yost
Assistant Director for Finance

Nathan Vanderford
Assistant Director for Research

Carla Repass
Assistant Director for Administration

FUNDRAISING UPDATE

LIGHT THE NIGHT

The Markey and Friends team for Light the Night, a fundraiser for the Leukemia & Lymphoma Society, raised $16,640. Samantha Eddington and Judy Malone, both nurses in the Markey Hematology Program, were team captains. Robin Fisher provided support for the Markey team and serves on the Executive Leadership Council for the Lexington office.

The office of Dr. Michael Karpf, UK executive vice president for health affairs, provided a $20,000 sponsorship.

Other UK teams included the Department of Psychology ($12,640), Clinical Lab ($2,028) and Bone Marrow Transplant ($2,338). More than 2,000 people attended the event, and more than $226,000 has been donated to the walk in total this year. Donations are accepted through the end of the year.

MAKING STRIDES FOR AMERICAN CANCER SOCIETY

The Markey team raised $908 for the Making Strides for the American Cancer Society race this year. The team held two events: a yard sale and chili cook-off.

SHARE YOUR ACCOMPLISHMENTS

The Markey Cancer Center would like to celebrate the successes of our faculty, staff and students, and we would like your help finding out about the great things that are happening.

You're invited to submit your recent accomplishment via the link below. You may also want to bookmark it for future reference; the online submission form will always be live so that you can submit new accomplishments as they happen.

https://redcap.rdmc.org/redcap/surveys/?s=WUVHdv

Some recent accomplishments are already highlighted in this issue's Noteworthy column - yours could be next!

2011 Markey Holiday Party

REPORT OF KENTUCKY ACCESS

TO THE

KENTUCKY HEALTH CARE IMPROVEMENT AUTHORITY

REPORTING PERIOD: 2ND QUARTER, FISCAL YEAR 2012

SUBMITTED: FEBRUARY 23, 2012

REPORT OF KENTUCKY ACCESS TO THE

KENTUCKY HEALTH CARE IMPROVEMENT AUTHORITY

(REPORTING PERIOD: 2ND QUARTER, FISCAL YEAR 2012)

1. WHAT ARE THE OVERALL GOALS AND OBJECTIVES FOR THE PROGRAM, AND HOW HAVE THOSE BEEN MET DURING THIS REPORTING PERIOD?

The overall goals and objectives of Kentucky Access were established by the Kentucky General Assembly through the enactment of House Bill 517 during the 2000 legislative session. Those goals and objectives include the following:

a. Implementation of "High Risk Pool" and HIPAA "Acceptable Alternative Mechanism"

One of the most important objectives of Kentucky Access is the implementation of a state-sponsored "high risk pool" pursuant to KRS 304.17B-001 *et seq*., to act as a safety net for individuals with high cost medical conditions. These individuals typically find it difficult or impossible to obtain private health insurance in the individual insurance market.

Since the inception of Kentucky Access on January 1, 2001, the numbers of applications received by the program have increased at a fairly steady pace from month-to-month and quarter-to-quarter, as shown in **Figure 1** below for the 2nd quarter of FY 2012 reporting period. **Figure 2** (next page) demonstrates the numbers of individuals applying for enrollment in Kentucky Access each quarter since the program began, 346 individuals applied during this reporting period, for an average of 434 applicants per quarter and 151 applicants per month.

FIGURE 1:

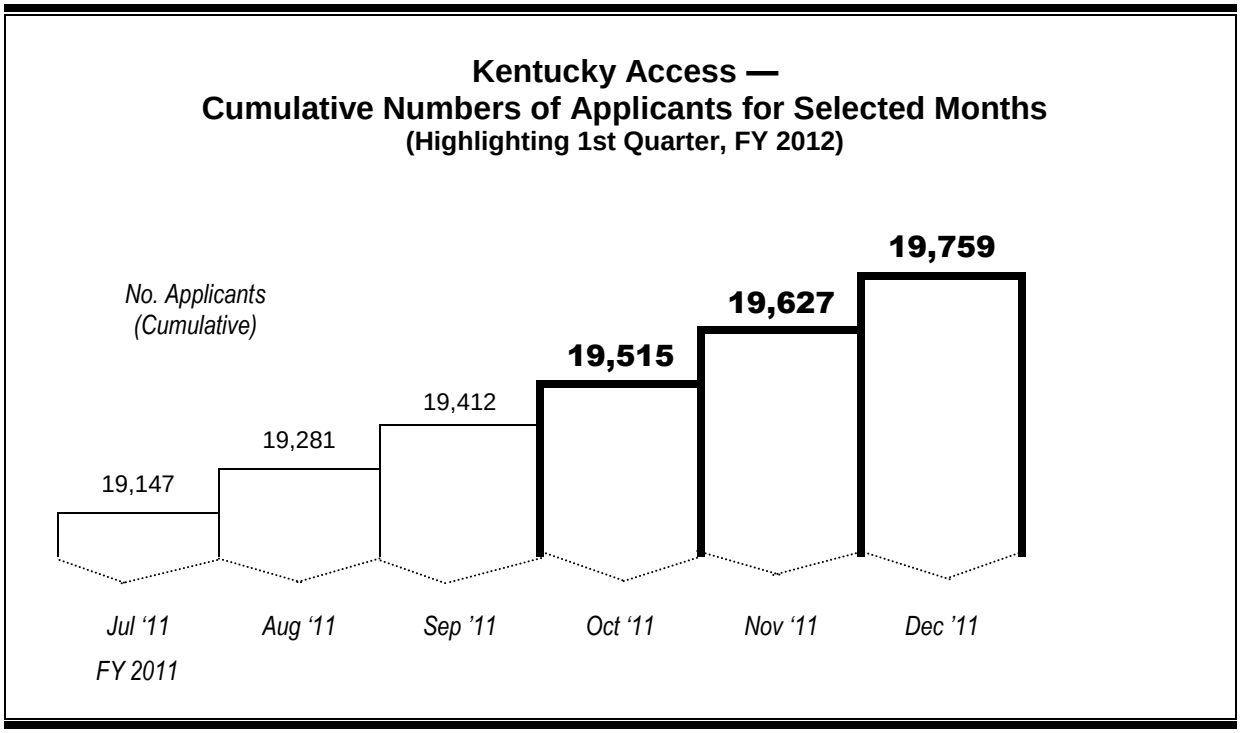


FIGURE 2:

Kentucky Access — Numbers of Applicants by Quarter
(Highlighting 1st Quarter, FY 2012)

Fiscal Year	No. of Applicants				Actual Yearly Total	Yearly Averages	
	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter		Avg. No. Applicants Per Quarter	Avg. No. Applicants Per Month
2001	-----	-----	288	270	558	279	93
2002	292	347	337	386	1,362	341	114
2003	369	379	428	435	1,611	403	134
2004	422	390	471	480	1,763	441	147
2005	446	517	540	432	1,935	484	161
2006	504	488	495	533	2,020	505	168
2007	479	496	548	462	1,985	496	165
2008	411	512	523	415	1,861	465	155
2009	469	509	537	504	2,019	505	168
2010	411	549	507	598	2,065	516	172
2011	542	603	482	428	2,055	514	171
2012	393	**346**			739	370	123
Combined Total and Yearly Averages					*19,973*	*434*	*151*

Figure 3 "annualizes" the number of applicants during FY 2001—the year Kentucky Access began operations—and establishes the annualized number as a baseline figure for the tracking of applicants through the current reporting period.

FIGURE 3:

Kentucky Access — Cumulative Numbers of Applicants by Quarter
(Highlighting 2nd Quarter, FY 2012)

Fiscal Year	Cumulative No. of Applicants				Annualized Yearly Total	Yearly Total Compared with Annualized Yearly Total for FY 2001
	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter		
2001	-----	-----	288	558	1,116 [1]	-----
2002	850	1,197	1,534	1,920	1,362	+ 22%
2003	2,289	2,668	3,096	3,531	1,611	+ 44%
2004	3,953	4,343	4,814	5,294	1,763	+ 58%
2005	5,738	6,239	6,788	7,229	1,935	+ 73%
2006	7,733	8,221	8,716	9,249	2,020	+ 81%
2007	9,728	10,224	10,772	11,234	1,985	+ 78%
2008	11,645	12,157	12,680	13,095	1,861	+ 67%
2009	13,564	14,073	14,610	15,114	2,019	+ 81%
2010	15,525	16,061	16,561	17,142	2,065	+ 82%
2011	17,669	18,302	18,715	19,026	1,884	+ 69%
2012	19,412	**19,759**			1,457	+ 31%

[1] FY 2001 Yearly Total calculated at 1,116 (6 month total of 558 annualized over 12 months)

As shown in **Figure 4** (next page) 16,266 of 19,412 total applicants had been approved for participation in and had benefited from the program by the end of the current reporting period. Of the remaining applicants, 178 had applications still being processed and 2,968 had been denied for failure to meet program eligibility requirements.

FIGURE 4:

Kentucky Access — Breakdown of Applicant Demographics and Choices (Highlighting 2nd Quarter, FY 2012)

	2nd QTR, FY 2012				2nd QTR, FY 2001 thru 2ND QTR, FY 2012			
	RECEIVED		APPROVED		RECEIVED		APPROVED	
	No.	%	No.	%	No.	%	No.	%
APPLICANTS (Appl's)								
Total Appl's	346	100%			19,759	100%		
Pending Appl's					- 173			
Total Appl's Adjudicated					19,586			
Denied Appl's					- 3,018			
Total Appl's Approved (New Eligibles)			302		16,568		16,568	
Terminated Appl's			- 17				-12,055	
Total Appl's after Terms. (Net Eligibles)			285	100%			4,513	100%
Appl's w/ Future Eff. Dates			- 10				-10	
Total Active Enrollees (Current Elig's)			275				4,503	
APPLICANT DEMOGRAPHICS								
Gender:								
Male	178	51%	151	53%	9,818	50%	2,296	51%
Female	168	49%	134	47%	9,941	50%	2,217	49%
Age:								
Average Age at Enrollment					51		49	
Region:								
Louisville Area (502)	97	28%	83	29%	6,136	31%	1,376	30%
Central & Northern Ky. (859)	87	25%	74	26%	5,107	26%	1,213	27%
Eastern Kentucky (606)	52	15%	51	18%	2,839	14%	703	16%
Western Kentucky (270)	110	32%	77	27%	5,677	29%	1,221	27%
Eligibility Category								
HIPAA			126	44%			1,854	41%
GAP			0	0%			1	0%
High Cost Condition			9	3%			219	5%
Insurance Rejection(s)			114	40%			1,940	43%
Higher Premium Quote			8	3%			277	6%
Dependent			28	10%			220	5%
Survivor			0	0%			2	0%
APPLICANT CHOICES								
By Benefit Plan								
Traditional Access (Indemnity)	**4**	**1%**	**4**	**1%**	**700**	**4%**	**110**	**3%**
$400 / $500 Deductible	4	1%	4	1%	700	4%	110	3%
Premier Access (PPO)	**212**	**62%**	**213**	**75%**	**16,377**	**82%**	**3,777**	**84%**
$400 / $500 Deductible	35	10%	36	13%	4,218	22%	862	19%
$1,000 Deductible	33	10%	31	11%	2,993	15%	695	16%
$1,500 Deductible	144	42%	146	51%	9,166	46%	2,220	49%
Preferred Access (PPO)	**51**	**15%**	**50**	**18%**	**2,464**	**13%**	**559**	**12%**
$750 Deductible	0	0%	0	0%	711	4%	96	2%
$1,500 Deductible	51	15%	50	18%	1,753	9%	463	10%
Child Only (PPO)	**23**	**7%**	**18**	**6%**	**124**	**1%**	**67**	**1%**
Undecided	**56**	**16%**	**0**	**0%**	**94**	**0%**	**0**	**0%**
By Deductible								
$400 / $500 Deductible	39	11%	40	14%	4,918	25%	972	22%
$750 Deductible	0	0%	0	0%	711	4%	96	2%
$1,000 Deductible	33	10%	31	11%	2,993	15%	695	15%
$1,500 Deductible	218	63%	214	75%	11,043	56%	2,750	61%
Undecided	56	16%	0	0%	94	0%	0	0%
By Rider								
Prescription Drug Rider	171	49%	178	62%	14,113	72%	3,320	74%
Mental Health Parity Rider	3	1%	4	1%	391	2%	66	2%
By Use of Agent								
No. Applicants Using Agent			136	48%			2,595	58%

By the end of the reporting period, 12,055 of the 16,568 "new eligibles" had terminated from the program and 10 had been approved with future effective dates, leaving a total of 4,503 "net eligibles." The classification of total applicants and "net eligibles" into various statistical categories is also illustrated in Figure 4: numbers are shown for both the reporting period alone and for the program as a whole through the end of the reporting period.

Kentucky Revised Statute (KRS) 304.17B-005(1) mandates that Kentucky Access function as the Commonwealth's "acceptable alternative mechanism" for portability of health care coverage under the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). *See* 42 U.S.C. Sec. 300gg-44(a) *et seq*. As a result, Kentucky Access is required to guarantee the issuance of health care coverage to persons who qualify as "eligible individuals" under HIPAA. Although a number of different factors must be considered in determining whether one ultimately qualifies as an "eligible individual," the core requirements involve documentation of at least eighteen months of prior, countable, creditable coverage, with the most recent such coverage being group, governmental, or church plan.

As shown in **Figure 4**, during the reporting period 126 (44%) of all net eligibles ("total applicants after terminations") were approved as "eligible individuals" under HIPAA. Between the inception of the program on January 1, 2001 and the end of the reporting period, 1,854 (41%) of all net eligibles had been approved under HIPAA. Kentucky Access is fulfilling its mission as an acceptable alternative mechanism for portability of health care coverage under HIPAA.

b. Increase in Competition in the Individual Health Insurance Market

One of the key strategies for restoring stability to the individual insurance market in Kentucky is to increase competition by expanding the number of private insurers participating in the market. The execution of this strategy involves the creation of Kentucky Access as a state-operated "high risk pool" designed to shoulder the burden of guaranteeing health care coverage to high-cost individuals.

Since Kentucky Access became operational on January 1, 2001, three (3) insurers have joined Anthem and Humana in the individual market and continue to provide individual coverage in Kentucky. Time Insurance Company and John Alden Life Insurance Company were each approved for return to the individual market in January, 2001; Golden Rule Insurance Company was approved to the individual market in 2005; and beginning July 1, 2010, the U.S. Cabinet for Health and Human Services began offering the federally sponsored Pre-Existing Condition Health Insurance Plan (PCIP). Additionally, four (4) insurers, Mega Life & Health Insurance Company, Physicians Mutual, Aetna Life Insurance Company and American Republic Insurance Company also returned to the individual market since Kentucky Access became operational. However, for various business reasons, these companies are no longer providing individual coverage in Kentucky.

As shown in **Figure 5** on the next page, there are currently seven (7) health care coverage choices for individuals, including Kentucky Access and PCIP.

FIGURE 5:

Kentucky Access —
Organizations Selling Individual Health Insurance in Kentucky
(Before and After Kentucky Access)

Before Kentucky Access	*After Kentucky Access*
• Anthem Blue Cross Blue Shield	• Anthem Blue Cross Blue Shield
• Humana Health Plan	• Humana Health Plan
	• Assurant Health/ Time Insurance Company
	• John Alden Life Insurance Company
	• Golden Rule Insurance Company
	• Kentucky Access
	• PCIP

2. EXPLAIN EACH MEASUREMENT USED BY THE PROGRAM TO DETERMINE WHETHER AN OBJECTIVE HAS BEEN MET.

Measurement of Kentucky Access's progress towards meeting overall goals and objectives can be accomplished through the monitoring of various factors. Because Kentucky Access is an insurance program, progress in many areas can be documented through specific data.

A determination of whether Kentucky Access is meeting its objective of establishing a "high risk pool" for high cost and other individuals, can be made by monitoring the numbers of individuals applying and qualifying for admission to the program. This data is shown in **Figures 1 – 4** on the preceding pages of this report.

A determination of whether Kentucky Access is fulfilling its mandate to serve as an "acceptable alternative mechanism" under HIPAA, can be accomplished by reviewing the numbers and percentages of individuals applying and qualifying for admission to Kentucky Access under the "HIPAA" eligibility category. This data is shown in **Figure 4** on the preceding pages of this report.

A determination of whether Kentucky Access is achieving its goal of restoring competition to the individual health insurance market can be made by periodically reviewing insurer filings at the Department of Insurance. (New insurers seeking admission to the individual insurance market must file with the Department all proposed benefit plans and the premium rates for such benefit plans; the rates and benefit plans are then reviewed by the Department for compliance with applicable laws and regulations). This data is shown in **Figure 5**, above. On an annual basis, monitoring of progress related to this objective may also involve a review of the numbers and types of benefit plans and cost-sharing options offered by insurers in the individual market, and the predictability and levels of rates for individuals purchasing insurance in the individual market.

3. WHAT CHALLENGES WERE ENCOUNTERED DURING THIS REPORTING PERIOD THAT ARE RELATED TO THE PROGRAM'S GOALS AND OBJECTIVES, ADMINISTRATION OR OTHER PROJECT FACTORS?

Financial management of the program through a time of increased costs and decreased appropriations continues to be a challenge. The program will continue to be closely monitored to ensure that it can continue to meet its obligations to its members.

4. PLEASE INDICATE WHETHER THE PROGRAM IS WORKING IN COLLABORATION WITH OTHER ORGANIZATIONS, OR DEPENDS ON OTHER ORGANIZATIONS TO MEET ITS GOALS AND OBJECTIVES.

Overall responsibility for supervising the operations of Kentucky Access rests with the Department of Insurance pursuant to KRS 304.17B-005 *et seq*. However, much of the day-to-day administration of the program is performed by other organizations. Kentucky Access relies heavily on these other organizations to help it meet its overall goals and objectives.

The Department has contracted with Louisville-based Anthem Health Plans of Kentucky, Inc., d/b/a Anthem Blue Cross and Blue Shield ("Anthem") for the provision of third party administrative services. Anthem is one of the oldest and largest health insurers in the State, with a wealth of experience in administering benefits for self-funded programs like Kentucky Access.

Kentucky Access leases several Anthem health care provider networks, including the Blue Traditional Network (used by Kentucky Access in its "Traditional Access" benefit plan); the Blue Access PPO Network (used by Kentucky Access in its "Premier Access" and "Preferred Access" benefit plans); the Express Scripts Pharmacy Network (used by Kentucky Access in all of its benefit plans); and the Anthem PPO Mental Health Network (used by Kentucky Access in all of its benefit plans). The Blue Traditional Network and the Blue Access Network are generally recognized as being the largest networks of their kinds in the state. Kentucky Access benefits from the significant fee discounts negotiated by Anthem with doctors, hospitals, and other providers in the various networks.

Although Anthem functions as network administrator and performs various other administrative services for Kentucky Access, it has subcontracted most of the day-to-day operation of the program to Indianapolis-based, ACS Health Administration ("ACS"). ACS performs a number of administrative services for Kentucky Access, including the processing of applications, premium billing and collection, customer service, claims payment, and marketing. With the Department's knowledge and consent, ACS has subcontracted the performance of disease management, utilization management and case management services to ACS Care and Quality Solutions, a utilization management company headquartered in Franklin, Wisconsin. As of October 2005, ACS has subcontracted a national "wraparound" hospital network with Health Systems International, LLC ("HSI") for use by enrollees when traveling to states outside the Anthem networks that we had previously reported as a challenge. The addition of a wraparound hospital network will save the program money by granting access to hospital discounts not currently available outside the Anthem networks and benefit the enrollees by limiting balance billing.

Anthem has subcontracted management of the pharmacy portion of the program to Express Scripts, Inc., a pharmacy benefits management company located in St Louis, Missouri.

5. PLEASE INDICATE HOW YOUR PROGRAM HAS MET OR PLANS TO MEET THE REQUIREMENT TO HOLD A PUBLIC HEARING ON THE EXPENDITURE OF FUNDS.

KRS 304.17B-003(6) specifically exempts Kentucky Access from holding public hearings on the expenditure of funds received from the Authority. The statute states: "[t]he authority shall assure that a public hearing is held on the expenditure of funds allocated under this section, *except for funds allocated to the Kentucky Access fund*. . . . " (Emphasis added). Due to this statutory exemption, Kentucky Access has not held a public hearing regarding the use of funds received from the Authority.

6. EXPLAIN ALL SOURCES OF FUNDING FOR THE PROGRAM AND ATTACH A REPORT OF EXPENDITURES FOR THE PREVIOUS QUARTER.

KRS 304.17B-021(4) provides that Kentucky Access shall be funded from the sources listed in Figure 6. Since the inception of the program, Kentucky Access had received funds from five of those funding sources:

FIGURE 6:

Kentucky Access — Authorized Funding Sources
(KRS 304.17B-021(4))

Funding Sources Previously and Currently Utilized by Kentucky Access

- Premiums paid by Kentucky Access enrollees
- Tobacco settlement funds distributed to Kentucky Access by the Kentucky Health Care Improvement Authority
- Annual assessments on supporting insurers
- Funds remaining on January 1, 2001 in the Guaranteed Acceptance Program account
- Interest or other earnings on the investment of moneys held in the Kentucky Access fund

Other Authorized Funding Sources

- Second assessments on supporting insurers
- Premium taxes collected under KRS Chapter 136 from any insurer, and any retaliatory taxes collected under KRS 304.3-270 from any insurer, for accident and health premiums that are in excess of the amount of the premium taxes and retaliatory taxes collected for the calendar year 1997
- Appropriations from the General Assembly
- Gifts, grants, or other voluntary contributions

Kentucky Access has made a concerted effort to ensure that management of revenues and expenditures is well-controlled. In addition to the accounting staff at the Department's main building in downtown Frankfort, the staff at the Department's Division of Kentucky Access includes an individual whose principal responsibility is the daily oversight of financial matters. In addition, the program has retained the services of a financial consultant to assist with the development and implementation of Kentucky Access financial policies and procedures, including internal controls.

Since Kentucky Access became operational on January 1, 2001, the program and its third party administrative subcontractors have undergone a number of financial audits and reviews. Thus far, the efforts to monitor and manage the program's finances have proven successful. The annual audit of the Kentucky Access fund by the state Auditor of Public Accounts (APA) pursuant to KRS 304.17B-029(2) for the period FY 2011 has been completed and the final audit report has been issued. For the 11th year in a row, Kentucky Access has received an "unqualified" (clean) audit opinion, with no material deficiencies noted.

Accrued revenues and expenditures for the **Reporting Period** are shown in Figure 7. All of the figures in Figure 7 are "unaudited."

FIGURE 7:

Kentucky Access — Revenues and Expenditures
Accrual Basis – Unaudited
(2nd Quarter, FY 2012)

REVENUES		
Enrollee Premiums	$	8,947,715
Master Tobacco Settlement Funds		6,996,100
Assessments on Supporting Insurers		(413,568)
Federal Grant		470,953
Premium Account – Interest		1,377
Tobacco Account – Interest		0
Assessment Account – Interest		(52)
Claims Account – Interest		170
Total Revenues	**$**	**16,002,696**
EXPENDITURES		
Benefit Expenses:		
Kentucky Access Medical Claims	$	8,542,287
Kentucky Access Pharmacy Claims		5,905,154
Increase (Decrease) in Ky. Access IBNR Reserve		0
Total Benefit Expenses		$14,447,441
Other Expenses:		
Kentucky Access Administrative Expenses		971,792
Kentucky Access Agent Referral Fees		6,350
Total Other Expenses		$ 978,142
Total Expenditures		**$ 15,425,583**
INCREASE / (DECREASE) IN FUND BALANCE	*** $**	**577,113**

* This figure represents the net of the revenues and expenditures for this reporting period. However, the cash balance at the end of this reporting period was $302,458.

Kentucky Access Approved Members by County
(As of December 31, 2011)

County	Active	Inactive	Total
Adair	15	42	**57**
Allen	20	49	**69**
Anderson	24	51	**75**
Ballard	4	38	**42**
Barren	54	128	**182**
Bath	9	22	**31**
Bell	13	34	**47**
Boone	133	351	**484**
Bourbon	15	56	**71**
Boyd	55	139	**194**
Boyle	31	75	**106**
Bracken	3	27	**30**
Breathitt	4	16	**20**
Breckinridge	10	40	**50**
Bullitt	61	221	**282**
Bulter	11	43	**54**
Caldwell	12	44	**56**
Calloway	70	126	**196**
Campbell	84	258	**342**
Carlisle	7	15	**22**
Carroll	8	20	**28**
Carter	7	46	**53**
Casey	10	21	**31**
Christian	44	171	**215**
Clark	34	88	**122**
Clay	4	19	**23**
Clinton	11	16	**27**
Crittenden	9	44	**53**
Cumberland	1	12	**13**
Daviess	133	364	**497**
Edmonson	9	38	**47**
Elliott	3	8	**11**
Estill	4	17	**21**
Fayette	432	906	**1338**
Fleming	22	24	**46**
Floyd	36	71	**107**
Franklin	30	111	**141**
Fulton	4	15	**19**
Gallatin	11	22	**33**
Garrard	8	50	**58**

County	Active	Inactive	Total
Grant	11	78	**89**
Graves	38	137	**175**
Grayson	40	81	**121**
Green	5	40	**45**
Greenup	36	95	**131**
Hancock	7	26	**33**
Hardin	65	201	**266**
Harlan	7	21	**28**
Harrison	10	48	**58**
Hart	10	47	**57**
Henderson	63	150	**213**
Henry	11	51	**62**
Hickman	5	20	**25**
Hopkins	41	142	**183**
Jackson	3	10	**13**
Jefferson	936	2619	**3555**
Jessamine	64	159	**223**
Johnson	22	50	**72**
Kenton	187	467	**654**
Knott	10	16	**26**
Knox	28	53	**81**
Larue	15	30	**45**
Laurel	61	114	**175**
Lawrence	14	30	**44**
Lee	4	11	**15**
Leslie	6	16	**22**
Letcher	10	21	**31**
Lewis	7	12	**19**
Lincoln	21	45	**66**
Livingston	9	28	**37**
Logan	28	73	**101**
Lyon	10	23	**33**
Madison	67	194	**261**
Magoffin	6	17	**23**
Marion	12	48	**60**
Marshall	36	111	**147**
Martin	6	12	**18**
Mason	14	29	**43**
McCracken	96	250	**346**
McCreary	19	31	**50**

County	Active	Inactive	Total
McLean	11	28	**39**
Meade	20	67	**87**
Menifee	2	6	**8**
Mercer	20	69	**89**
Metcalfe	8	11	**19**
Monroe	12	19	**31**
Montgomery	26	60	**86**
Morgan	12	25	**37**
Muhlenburg	17	82	**99**
Nelson	49	108	**157**
Nicholas	7	12	**19**
Ohio	14	48	**62**
Oldham	101	255	**356**
Owen	8	30	**38**
Owsley	1	3	**4**
Pendleton	23	51	**74**
Perry	11	39	**50**
Pike	63	134	**197**
Powell	6	19	**25**
Pulaski	92	183	**275**
Robertson	0	6	**6**
Rockcastle	8	26	**34**
Rowan	17	23	**40**
Russell	21	41	**62**
Scott	42	102	**144**
Shelby	75	146	**221**
Simpson	19	63	**82**
Spencer	16	46	**62**
Taylor	23	72	**95**
Todd	7	30	**37**
Trigg	16	52	**68**
Trimble	7	19	**26**
Union	18	42	**60**
Warren	128	406	**534**
Washington	7	31	**38**
Wayne	11	42	**53**
Webster	17	53	**70**
Whitley	28	55	**83**
Wolfe	2	13	**15**
Woodford	43	94	**137**

Total Active:	4,503
Total Inactive:	12,055
Grand Total:	16,558

Kentucky Health Care Improvement Authority
Second Quarter FY12
Tobacco Prevention and Cessation Program
Kentucky Department for Public Health

1. **Please summarize any progress or achievement toward the goals of your *program that have been met during this reporting period.***
   - Adult Smoking: 24.8% of adults (over the age of 18) are current smokers compared to 25.6% in 2009 (Source: 2010 Behavioral Risk Factor Surveillance System). Current smoking has declined 20% since 2003.
   - Middle School current smokers 9% compared 9.75 in 2008. Since 2000, middle school smoking has declined 60%. (Source: 2010 Kentucky Youth Tobacco Survey)
   - High School current smokers 26.6% compared to 26.8% in 2008. Since 2000, high school smoking has declined 30%. (Source: 2010 Kentucky Youth Tobacco Survey)
   - Thirty-one municipalities have enacted smokefree policies. 27 are city or county ordinances; 4 are Board of Health Regulations. Eighteen municipalities in Kentucky, or approximately 34 percent of Kentuckians, are covered by comprehensive ordinances or regulations requiring 100% smoke-free workplaces. Bullitt County adopted a comprehensive smoke-free regulation scheduled for implementation September 15, 2011.

2. ***Please provide a report on the expenditure of tobacco settlement funds during this reporting period.***
   See attached template.

3. ***Please indicate if your program has met the requirement to hold a public hearing on the expenditure of funds during this reporting period. If so, please include documentation regarding the hearing (for example, notices publicizing the hearing, handouts, minutes, media coverage, etc.) Please indicate any comments received, positive or negative, on the proposed use of funds.***

   A Public Hearing was held August 16, 2011 in conjunction with the Health Care Improvement Authority's quarterly meeting.

Second Quarter Program Highlights

- Media campaign: Using a combination of Stimulus and CDC grant funds, the Tobacco Program contracted with Doe Anderson to develop a media campaign on the Health Effects of Secondhand Smoke. The media campaign includes television ads, radio, Facebook banners, a landing page and fact sheets for the DPH Tobacco Program web site, Kentucky News Network (audio news releases), and billboards.
    - You can see the television ads at http://www.youtube.com/user/KyTobaccoPrevCess
    - Listen to radio

DOE-SecondhandSmoke RAD30 MIX.mp3

- Tobacco Control Manager Vacancy: The merit position posted in early December. Irene Centers, Health Promotion Branch Manager, continues to oversee the Tobacco Program until a replacement is hired.
- Coordinated Chronic Disease Prevention and Health Promotion Grant: Chronic Disease Prevention Branch received a grant to develop a coordinated state plan that includes all program in the Health Promotion Branch (i.e. Tobacco Prevention and Control). A combination of conference calls, webinars, and face-to-face meetings were utilized to develop a framework. A stakeholders meeting was held November 29 at the Kentucky History Center with approximately 200 people in attendance. The grant goals are 1) ensure that every state has a strong foundation for chronic disease prevention and health promotion; 2) maximize the reach of categorical chronic disease programs in states; 3) provide leadership and expertise to work collaboratively across chronic disease conditions and risk factors; 4) improve CDC's service to state health departments in chronic disease and health promotion.
- SPE Policy Consortium: The Tobacco Program Manager was asked to serve on this Policy Consortium (DPH signed a Memorandum of Understanding). The Substance Abuse Branch received a Strategic Prevention Enhancement (SPE) grant with primary prevention as the focus, build emotional health, prevent or delay onset of and mitigate symptoms of substance use and mental illness.
- FDA CTP Retail Education: The Tobacco Program, Department of Alcoholic Beverage Control, and the Substance Abuse Prevention Program are working together to develop a tobacco retailer education program. The three programs each have a contract or grant related to illegal sales to minors. The Retailer Education program is voluntary, however they will benefit from a schedule of lower penalties for retailers who have completed a training program that complies with the standards set by FDA.
- FDA CTP Multi-State Conference: The Tobacco Program, Department of Alcoholic Beverage Control, and Substance Abuse Prevention Program are hosting a Multi-State Conference in May on States "The Tobacco Control Act: *Compliance Checks and Retailer Education.*"

		TOBACCO FUNDS	AGENCY FUNDS	FEDERAL FUNDS (INCLUDING FS)	TOTAL
110	Salaries And Wages	0.00	0.00	103,618.19	103,618.19
120	Fringe Benefits	0.00	0.00	44,307.48	44,307.48
130	Other Personnel Costs	0.00	0.00	16.00	16.00
140	Pro Contract (Inc Per Serv)	4,145.27	0.00	259,762.39	263,907.66
169	Indirect Personnel Costs	0.00	0.00	10,985.02	10,985.02
	Total Personnel Costs	**4,145.27**	**0.00**	**418,689.08**	**422,834.35**
220	Rentals	1,366.46	0.00	1,135.54	2,502.00
230	Maintenance And Repairs	0.00	0.00	21,537.00	21,537.00
250	Miscellaneous Services	0.00	0.00	6,086.00	6,086.00
320	Supplies	821.32	0.00	368.58	1,189.90
340	Commodities	0.00	0.00	0.00	0.00
360	Travel Exp & Exp Allowances	1,049.18	0.00	2,742.26	3,791.44
370	Misc Commodities & Other Exp	0.00	0.00	1,910.00	1,910.00
508	Indirect Operating Expense	0.00	0.00	15,228.98	15,228.98
	Total Operating Expenses	**3,236.96**	**0.00**	**49,008.36**	**52,245.32**
410	Grants	19,536.68	0.00	112,487.62	132,024.30
430	Fin Assist/Non-State Agencies	1,306,290.48	0.00	405,706.97	1,711,997.45
	Total Grants, Loans, Benefits	**1,325,827.16**	**0.00**	**518,194.59**	**1,844,021.75**
	Total Expenditures:	**1,333,209.39**	**0.00**	**985,892.03**	**2,319,101.42**

Expenditures by Quarter by Fund

First Qtr.	501,245.00	0.00	345,746.29	846,991.29
Second Qtr.	606,421.17	0.00	408,744.17	1,015,165.34
Third Qtr.	225,543.22	0.00	231,401.57	456,944.79
Total:	**1,333,209.39**	**0.00**	**985,892.03**	**2,319,101.42**

Kentucky Lung Cancer Research Program

2nd Quarter Report
Fiscal Year 2012

University of Louisville
James Graham Brown Cancer Center

February 2012

Kentucky Lung Cancer Research Program

Long Term Goals

Source: Governance Board Strategic Plan

Investigator-Initiated Research

1. Review current scientific knowledge and identify critical gaps
2. Develop new hypotheses
3. Design the most direct pathways to test these hypotheses
4. Utilize and develop animal models in the analysis of lung cancer
5. "Translate" new findings and technologies into innovative clinical applications
6. Test the most promising new prevention and treatment strategies in clinical trials.

Research in Early Detection & Prevention

1. Conduct screening and early detection research using available and applicable tools in key geographic areas of the state
2. Expand and refine methodologies for risk-factor delineation
3. Validate the use of methodologies for lung cancer screening
4. Identify and develop methodologies for lung cancer prevention
5. Maintain and expand the biospecimen repository for use by lung cancer researchers
6. Capitalize on partnerships with regional and local hospitals and clinics to build an early detection network where research is integral to the relationship.

Kentucky Clinical Trial Network (CTN)

1. Increase number of Kentuckians with access to and participating in lung cancer clinical trials
2. Develop and maintain a critical mass of trained professional staff to support multiple-site clinical trials
3. Offer and manage industry-sponsored lung cancer clinical trials through the Network
4. Identify and develop investigator-initiated clinical trials at both universities that can be offered to patients in diverse settings
5. Continually improve the Network's services with input from practicing Kentucky physicians.

NCI-Designation as Cancer Centers

1. Expand the base of cancer research expertise, particularly in translational research, with the recruitment of both promising young scientists and established investigators working at the front lines of cancer research
2. Develop diverse cancer research programs with a high degree of inter- and intra-team collaboration
3. Provide and promote interactive research opportunities
4. Offer expanded innovative clinical trials, building on combined research underpinnings of the two canters.

Kentucky Health Care Improvement Authority

Tobacco Settlement Funding Report

1. Please summarize any progress or achievement toward the goals of your program that have been met during this reporting period.

As delineated above, the primary goals set forth and approved by the Governance Board drive the Kentucky Lung Cancer Programs at both the University of Kentucky and the University of Louisville. The mandate is to "help Kentuckians gain or retain their good health" and to "build the nation's centerpiece of lung cancer research in Kentucky". The James Graham Brown Cancer Center at the University of Louisville utilizes these funds to recruit new faculty, develop sustainable research programs and enhance clinical trials offered to the citizens of Kentucky. Specifically these funds help to support five critical focus areas:

A. NCI Designation
    i. Faculty Recruitment
    ii. Program Development
    iii. Core Support
B. Clinical Trials Program
C. Early Detection Research Program
D. Investigator-Initiated Granting Program
E. Administration

In addition to the infrastructure needs of a developing cancer center, the KLCR Program provides the additional critical resource of funding a Competitive Lung Cancer Research Grants program. These funds support early stage research projects leading to future funding from the federal government and other funding entities, and, in a number of cases, to clinical trials.

Progress in each of the primary areas continues to help build the Lung Cancer research and clinical trials portfolio at the University of Louisville James Graham Brown Cancer Center.

Second Quarter Highlights include:

- Twenty-one Cycle 11 applications for Investigator-Initiated research funding were received and are being reviewed (awardees will be announced in the next quarter).
- Eight publications resulting from Investigator-Initiated grants were published.
- Radiation Oncology was awarded a full three-year accreditation by the joint American College of Radiology / American Society of Therapeutic Radiology and Oncology.

A. NCI Designation

The path to NCI Designation requires strong research programs and the recruitment of key faculty essential to the growth of the James Graham Brown Cancer Center.

Several researchers were recruited in the previous two quarters, and – while no one was recruited in this quarter – several faculty searches are open, as delineated below.

Additional faculty searches are in progress, including:

• The James Graham Brown Cancer Center and the Department of Medicine are conducting a national search for a new Chief of the Division of Medical Oncology. This position is critical to a strong cancer center. Requirements for this position include a passion for education, experience in leading an established research program in clinical and translational research, and experience providing patient care with an emphasis on lung cancer. The position includes a $2,000,000 endowed chair – the result of a generous gift by the KLCR Program. The interview process is underway, with additional interviews held in this quarter.

In addition, after careful evaluation of the research programs, the following focused faculty searches are underway:

• The JGBCC is recruiting a medical oncologist whose primary focus will be on patient care. A national search has been instituted and interviews will begin in the next quarter.

• The JGBCC Kosair Pediatric Cancer Research Institute launched a national search for two additional faculty with strong records in molecular target identification and an interest in pediatric cancers. The Institute faculty are working closely with other JGBCC researchers, especially those in the Molecular Targets and Structural Biology Programs. While the new faculty won't work directly on lung cancer, many therapies work on more than one cancer and drugs designed for children also are used for adult cancers. One new faculty member was recruited at the end of the last fiscal year (Dr. Levi J. Beverly) along with a medicinal chemist (Joseph Burlison), with up to two additional positions to be filled.

• In August 2010 the James Graham Brown Cancer Center received a $3.15 million grant from the Leona M. and Harry B. Helmsley Charitable Trust to support the cancer research being done on (tobacco) plant-based pharmaceuticals by the JGBCC Owensboro research group. As a result, a national search was launched in the last fiscal year to recruit two additional faculty members to this group. Several candidates have been interviewed but the search continues.

In addition, in the last quarter, the American Society for Therapeutic Radiology and Oncology and the American College of Radiology awarded a full three-year accreditation to the Department of Radiation Oncology at the JGBCC. This accreditation program provides radiation oncologists with third party, impartial peer review and evaluation of patient care. The facility's personnel, equipment, treatment planning and treatment

records as well as patient safety policies, and quality control/quality assessment activities are assessed. The full 3-year accreditation is the highest level of accreditation awarded by the joint committee.

B. Clinical Trials Program

The Kentucky Lung Cancer Program provides valuable support for the James Graham Brown Cancer Center's lung cancer clinical trials program. The JGBCC has sixteen active clinical trials specific to lung cancer, with a couple more pending. We are actively accruing patients to investigator-initiated trials, cooperative group trials as well as those sponsored by pharmaceutical companies. Our clinical trial investigators, most notably Dr. Goetz Kloecker, who runs the multidisciplinary lung oncology clinic, are working with the Kentucky Clinical Trials Network to open JGBCC-initiated trials within the KCTN. In addition to KCTN trials, the lung cancer trials include one trial where the initial research was funded by the KLCR Program: the early detection metabolomics analysis of primary lung cancer. In addition, a protocol for the lung cancer database and specimen repository (partially funded by the KLCR Program) is available.

Other KLCR Program Investigator-Initiated funded projects are moving toward clinical trials, most notably those being pursued by Dr. Douglas Taylor (funded in Cycle 7) and by Dr. Jason Chesney (funded in Cycle 4). Dr. Chesney filed an investigational new drug (IND) application for his compound 3PO with the FDA in this quarter.

C. Early Detection Program

There are several exciting, on-going early detection projects underway at the James Graham Brown Cancer Center. The most significant include:

• JGBCC investigators have enrolled more than 60 patients in a novel clinical trial studying lung cancer metabolism. Their technique determines the utilization of glucose at the "atomic-level". The research team, led by Dr. Andrew Lane and thoracic surgeon, Dr. Michael Bousamra, is using this unique line of research to characterize differences between normal and malignant lung tissue. There already have been several important outcomes from this research, including identification of a number of new targets for therapeutic intervention. We anticipate that this approach will continue to provide advances in earlier detection of lung cancer leading to more successful outcomes. This new approach also may be a practical way to screen individuals who are at high risk of developing lung cancer.

In the next quarter, these investigators will submit a multi-part 'program project' application to the National Cancer Institute. This application will take into account minor reviewer comments and those of the external advisory committee – all comments were positive and the criticisms minor. This large, multi-project grant requests funding of $2,000,000 per year.

• JGBCC investigators are developing a radiolabeled aptamer that holds promise as a diagnostic imaging agent that targets human cancers. Drs. John Trent and Paula Bates are expanding the utilization of this compound by attaching a radioactive

molecule that may be used as a tracer compound to detect cancer cells by Positron Emission Tomography (PET) scanning. There also is a move to use this technology for pediatric cancers.

• JGBCC investigators are utilizing microcalorimetry to analyze serum from lung cancer patients and individuals at high risk for lung cancer. This work, led by Dr. Jonathan B. Chaires, shows remarkable specificity for lung cancer detection, as it has for a number of other diseases. The investigators have determined the signature thermogram characteristics of the various stages of lung cancer progression. The data obtained provide clear proof-of-principle for the utility of plasma thermograms in the diagnosis of lung cancers. The investigators are working to obtain thermograms for individual patients over the entire course of their diagnosis, therapy and follow-up. Ultimately they plan to use this tool for the diagnosis and therapeutic monitoring of lung cancers as well as a number of other diseases.

In addition to the above projects, other investigators at the JGBCC are collaborating to investigate novel methods for the early detection of lung cancer:

• Drs. A. Bennett Jenson and Shin-je Ghim are investigating the role of human papillomavirus and polyomavirus in the etiology of human lung cancer. Their work holds promise for the identification of a group of patients who have a much higher risk of developing lung cancer than the general population.

• Based on their "first in the world" metabolomic study of lung cancer (as noted above), Drs. Andrew Lane, Teresa Fan, Michael Bousamra and Richard Higashi have identified a number of lung cancer biomarkers. They are developing the technology to utilize this information in a lung cancer "breath test". This technique holds promise as an inexpensive, non-invasive means for the very early detection of lung cancer. The investigators have developed a test device and obtained some preliminary data, and are working toward implementing a pilot study.

• Expression of specific microRNAs in lung biopsies correlates with lung tumor presence, stage, prognosis and response to treatment. Dr. Douglas Taylor and his team are correlating the presence of specific exosomal microRNAs with clinico-pathologic characteristics. Once all of the microRNAs associated with these exosomes are identified, a larger, blinded validation trial will be conducted. This approach will allow the application of microRNA profiling to lung cancer screening, early detection, and disease monitoring

D. Investigator-Initiated Lung Cancer Research Grant Program

The investigator-initiated granting program, along with strong recruitment (as discussed above), continues to produce a robust pipeline for new approaches to lung cancer research.

Cycle 11, announced at the JGBCC in the previous quarter, resulted in the submission of twenty-one applications. External reviewers (outside the state of Kentucky) were identified and the review process is underway. The KLCR Program will

fund four, two-year grants with the awardees identified in the next quarter. Applications received:

- The primo vascular system: A novel entity associated with lung cancer growth and metastasis – P.J. Bates
- Mechanisms of lung cancer promotion by crystalline silica induced inflammation – H. Bodduluri
- Altered mitochondrial function in lung adenocarcinoma cells – B.J. Clark
- Reactivating polymorphonuclear neutrophils to fight lung cancer – G.J. Clark
- ß-glucan modulates differentiation and function of myeloid-derived suppressor cells in lung cancer – C. Ding
- A novel, non-invasive, image-based system for early diagnosis of malignant lung nodule – A. El-Baz
- Lung nodule detection and categorization from LDCT - A data-driven approach – A.A. Farag
- Imaging EGF receptor and EGF receptor mutation on nonsmall cell lung cancer – H. Guo
- Enhancement of oncolytic adenovirus therapeutic efficacy by combination with Temozolomide – J.G. Gutierrez
- DHEA regulation of oncomiR miR-21 in nonsmall cell lung cancer – C.M. Klinge
- Nanotube antibody arrays for profiling circulating cancer cells in peripheral blood of patients with lung cancer – G.H. Kloecker
- Biomarker discovery in the plasma lipid metabolome in early stage NSCLC – A.N. Lane
- Activating Bax as a therapeutic strategy against lung cancer – C. Li
- The role of mi301a in NF-kappaB activation and lung cancer – Y. Li
- Tight junction protein, Claudin 9, as a novel mediator of lung cancer metastasis – R.K. Sharma
- Novel cancer chemotherapeutics targeting mitosis – J.C. States
- Procathetpsin D in lung cancer: Involvement in chemoresistance and development of cancer screening – V. Vetvicka
- Targeting sphingolipid metabolism for the treatment of lung cancer – B. Wattenberg
- New approaches for eliminating lung cancer initiating stem cells – K. Yaddanapudi
- Targeting indoleamine 2,3 dioxygenases for development of a therapeutic vaccine against lung cancer – E. Yolcu
- Targeting cyclin E for lung cancer prevention – H.S. Zhou

While progress in obtaining larger national grants is a little slower than we might hope due to the amount of preliminary work required and the nature of the grants, the research being conducted by a number of investigators has great potential to benefit future lung cancer patients. As mentioned above, one large program project grant will be submitted in the next quarter, and three more are in the planning stages with submission anticipated in the next year.

Publications by Investigator-Initiated funded investigators in this quarter

Akter S, Clem BF, Lee HJ, **Chesney J**, *Bae Y*. Block copolymer micelles for controlled delivery of glycolytic enzyme inhibitors. *Pharmaceutical Research* 2011 Oct 28. [Epub ahead of print] PubMed PMID: 22033882. [Chesney / Bae – Cycle 10]

Siow D, **Wattenberg B**. The compartmentalization and translocation of the sphingosine kinases: mechanisms and functions in cell signaling and sphingolipid metabolism. *Critical Reviews in Biochemistry and Molecular Biology* Oct;46(5):365-75, 2011. Doi: 10.3109/10409238.2011.580097. Review. PubMed PMID: 21864225; PubMed Central PMCID: PMC3183286. [Wattenberg – Cycle 9]

Siow DL, Anderson CD, Berdyshev EV, Skobeleva A, Natarajan V, Pitson SM, **Wattenberg BW**. Sphingosine kinase localization in the control of sphingolipid metabolism. *Advances in Enzyme Regulation* 51(1):229-44, 2011. PubMed PMID: 21075134; PubMed Central PMCID: PMC3079002. [Wattenberg – Cycle 9]

Vetvicka V, Saraswat-Ohri S, Vashishta A, Descroix K, Jamois F, Yvin JC, Ferriéres V. New 4-deoxy-(1→3)-ß-D-glucan-based oligosaccharides and their immunostimulating potential. *Carbohydrate Research* Oct 18;346(14):2213-21, 2011. PubMed PMID: 21802071. [Vetvicka – Cycle 8]

Taylor DD, Gercel-Taylor C. Exosomes/microvesicles: mediators of cancer-associated immunosuppressive microenvironments. *Seminars in Immunopathology* 33(5):441-54, 2011. Review. PubMed PMID: 21688197. [Taylor & Taylor – Cycle 7]

Klinge CM, Radde BN, Imbert-Fernandez Y, Teng Y, Ivanova MM, Abner SM, Martin AL. Targeting the intracellular MUC1 C-terminal domain inhibits proliferation and estrogen receptor transcriptional activity in lung adenocarcinoma cells. *Molecular Cancer Therapy* Nov;10(11):2062-71, 2011. PubMed PMID: 21862684; PubMed Central PMCID: PMC3213286. [Klinge – Cycle 7]

Imbert-Fernandez Y, Radde BN, Teng Y, Young WW Jr, Hu C, **Klinge CM**. MUC1/A and MUC1/B splice variants differentially regulate inflammatory cytokine expression. *Experimental Eye Research* Nov;93(5):649-57, 2011. PubMed PMID: 21854773; PubMed Central PMCID: PMC3221811. [Klinge – Cycle 7]

Miller MC, Le HT, Dean WL, Holt PA, Chaires JB, **Trent JO**. Polymorphism and resolution of oncogene promoter quadruplex-forming sequences. *Organic Biomolecular Chemistry* Oct 26;9(22):7633-7, 2011. PubMed PMID: 21938285. [Trent – Cycle 6]

E. Administration

While the focus of the James Graham Brown Cancer Center (JGBCC) is on patient care and research, more emphasis is placed on research and the ultimate goal of NCI designation. The Administrative team supports all phases of the Kentucky Lung Cancer Program.

The Administrative team works both independently and with the Administration of the Markey Cancer Center to leverage KLCRP and other support to build strong and collaborative centers to provide the best care to the citizens of Kentucky.

In the previous quarter, the Administrative team announced the Cycle 11 funding opportunity, with an emphasis on junior investigators, and – in this quarter – received 21 applications. The applications are out for review. Awardees will be announced in the next quarter report.

The Administrative team also provided support to the funded investigators of the KLCRP and to the other initiatives of the program, all of which required some degree of assistance.

In addition, the KLCRP Strategic Plan is being reviewed and rewritten to bring the program up-to-date. A draft will be available in the next quarter.

1. **Please indicate any challenges that were encountered during this reporting period related to the program's goals and objectives, administration or other project factors.**

During this reporting period no new challenges were encountered relevant to the program goals. However, the major challenges to obtaining NCI designation remain unchanged: recruitment of additional faculty in all program areas, improvement in NIH/NCI funding levels, and development of space for future growth.

2. **Please provide a report on the expenditure of tobacco settlement funds during this reporting period.**

Initiative	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter	Annual
Administration	$ 16,113	$ 20,094			$ 36,207
NCI Designation	$211,237	$277,575			$488,812
Clinical Trials	$ 66,208	$ 60,650			$126,858
Early Detection	$ 42,430	$ 9,106			$ 51,536
Competitive Research Grant	$165,418	$112,176			$277,594
Total	$501,406	$479,601			$981,007

3. **Please indicate if your program has met the requirement to hold a public hearing on the expenditure of funds during this reporting period. If so, please include documentation regarding the hearing (for example, notices publicizing the hearing, handouts, minutes, media coverage, etc.). Please indicate any comments received, positive or negative, on the proposed use of funds.**

A public meeting of the Kentucky Lung Cancer Research Program Governance Board was not held in this quarter. The last public meeting was held on September 28, 2011. No public comments were received. The next meeting of the Governance Board is anticipated to be in the fourth quarter of this year.

KLCR Program Governance Board Members

Harry W. Carloss, M.D., Chair and Member-at-large
John W. Eaton, Ph.D., University of Louisville
B. Mark Evers, M.D., University of Kentucky
Donald M. Miller, M.D., Ph.D., University of Louisville
Timothy W. Mullett, M.D., University of Kentucky
Dan Flanagan, Council on Postsecondary Education
Joe Graviss, Council on Postsecondary Education
Rajan R. Joshi, M.D., Council on Postsecondary Education
James P. Roach, M.D., Member-at-Large